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Rules and Regulations

Title 7—AGRICULTURE

Chapter I—Agricultural Marketing Service (Standards, Inspections, Marketing Practices), Department of Agriculture

SUBCHAPTER C—REGULATIONS AND STANDARDS UNDER THE FARM PRODUCTS INSPECTION ACT

PART 56—GRADING OF SHELL EGGS AND UNITED STATES STANDARDS, GRADES AND WEIGHT CLASSES FOR SHELL EGGS

Miscellaneous Amendments

Under authority contained in the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621–1627), the United States Department of Agriculture hereby amends the regulations governing the grading of shell eggs (7 CFR Part 56), as stated below:

Statement of considerations. The amendments eliminate yolk centering as a factor of interior egg quality, raise the minimum requirements for eggs packed under both the Fresh Fancy Quality or U.S. Grade AA and U.S. Grade A quality control programs and raise the standards of U.S. Grade A eggs.

The amendments also delete Grade C from the U.S. Consumer Grades for shell eggs, modify the present classification of eggs with slight shell stains, make minor changes in facility requirements, delete certain paragraphs that are repetitious and relocate certain items for the sake of clarity and continuity.

Notice of the proposed issuance of amendments to the Regulations Governing the Grading of Shell Eggs and United States Standards, Grades and Weight Classes for Shell Eggs was published in the FEDERAL REGISTER of April 4, 1963.

The majority of comments received pertained to the change in the moving average of eggs qualifying for Fresh Fancy Quality or Grade AA under the quality control program. While there was quite a difference in the opinions expressed by interested persons, the Department, after careful consideration of all relevant data, maintains that it is essential that the moving average be changed from 72 Haugh units to 74 Haugh units.

Until 1959, the minimum Haugh unit value for eggs of AA quality was 79. This figure was used by both breeders and research workers. Several years ago marketing firms started using this system of grading and many requested that the Department initiate a study to determine if a certification program could be developed based on the use of the Haugh unit system. Such a program was subsequently developed and during the development Poultry Division marketing specialists and graders studied both candled and broken-out egg quality in plants in various areas throughout the country. They found that the figure of 79 Haugh units was unrealistic and not in keeping with the level of egg quality generally available.

In June 1959, the Department proposed that the minimum for AA quality be changed from 79 to 72 Haugh units. Substantial agreement by the industry was found and the change became effective in September 1959. Evidence then indicated that 72 Haugh units was a realistic and obtainable figure for the minimum standard and records since that time have confirmed this. Therefore, the Department is not changing the minimum standard for Grade AA or Fresh Fancy Quality eggs, and is changing only the minimum moving average requirement for flocks on the quality control program in order to be assured that such eggs are above 72 Haugh units. A statistical analysis and evaluation of the data collected during the years the program has been in operation indicates that a change in the minimum moving average from 72 to 74 Haugh units will assure that the weekly average will be above 72 Haugh units 84 percent of the time when the flocks are at the minimum moving average. When flocks are at a moving average of only 72 Haugh units, the weekly average will be above 72 Haugh units only 50 percent of the time. The same is true for eggs packed under the Grade A quality control program. The minimum moving average must be 62 Haugh units in order to be assured that such eggs are consistently above the minimum standard for Grade A eggs of 60 Haugh units.

There was not general agreement on the proposal to change the wholesale grades and consequently no change will be made.

The wording of the section pertaining to tolerances for consumer grades has been changed from what was in the proposal and an additional table has been added to that section to better illustrate the tolerances permitted for an individual case or carton within a lot. Such a change does not alter the meaning or intent of what was contained in the proposal except that the tolerance for an individual carton is not as restrictive as was proposed and is in keeping with recommendations received regarding the proposed amendment.

This regulation pertains only to grading activities and all sections and paragraphs containing any reference to inspection activities have been rewritten to eliminate such wording. The following have been rewritten solely for this purpose: Heading—Subpart A; § 56.2; § 56.6; Heading preceding § 56.10; § 56.10 (c); § 56.13; § 56.15; § 56.16; Heading preceding § 56.20; § 56.20; § 56.21; § 56.22; § 56.23; § 56.24; § 56.30; § 56.31 (a) (1), (4) and (6); § 56.45(a); § 56.46 (b); § 56.51; § 56.52 (a) (1) and (a) (6); § 56.62; first paragraph of § 56.100; and § 56.215(c). In addition, a new § 56.54 has been added to provide a modified resident-type service to cover certain grading situations.

The remaining portion of the amendments are essentially the same as those proposed except for changes in wording for clarification purposes.

After consideration of all relevant material presented, the amendments hereinafter set forth are promulgated.

The amendments are as follows:

1. Change Subpart A heading above § 56.1 to read: "Subpart A—Grading of shell eggs".

2. Combine § 56.1 and § 56.2 and change first paragraph of § 56.1 to read:

§ 56.1 Meaning of words and terms defined.

For the purpose of the regulations in this part, words in the singular shall be deemed to import the plural and vice versa, as the case may demand, and unless the context otherwise requires, the following terms shall be construed, respectively, as follows:

3. Change § 56.1(h) to read:

(h) "Eggs of current production" means shell eggs which have moved through usual marketing channels since the time they were laid and have not been held in refrigerated storage in excess of 30 days. "Refrigerator or storage eggs" means shell eggs which have been held under refrigeration for a period of more than 30 days.

4. Delete § 56.1(l) and renumber paragraphs (m) through (aa) to read (l) through (y) respectively.

5. Renumber § 56.2a to read § 56.2 and change to read:

§ 56.2 Designation of official certificates, memoranda, marks, other identifications and devices for purposes of the Agricultural Marketing Act.

Subsection 203(h) of the Agricultural Marketing Act of 1946, as amended by Public Law 272, 84th Congress, provides criminal penalties for various specified offenses relating to official certificates, memoranda, marks or other identifications, and devices for making such marks or identifications, issued or authorized under section 203 of said act, and certain misrepresentations concerning the grading of agricultural products under said section. For the purposes of said subsection and the provisions in this part, the terms listed in this section shall have the respective meanings specified:

(a) "Official certificate" means any form of certification, either written or printed, used under this part to certify with respect to the sampling, class, grade, quality, size, quantity, or condition of products (including the compliance of products with applicable specifications).

(b) "Official memorandum" means any initial record of findings made by an authorized person in the process of

grading or sampling pursuant to this part, any processing or plant-operation report made by an authorized person in connection with grading or sampling under this part, and any report made by an authorized person of services performed pursuant to this part.

(c) "Official mark" means the grade mark and any other mark, or any variations in such marks approved by the Administrator and authorized to be affixed to any product, or affixed to or printed on the packaging material of any product, stating that the product was graded, or indicating the appropriate U.S. grade or condition of the product, or for the purpose of maintaining the identity of products graded under this part, including but not limited to, those set forth in § 56.36.

(d) "Official identification" means any United States (U.S.) standard designation of class, grade, quality, size, quantity, or condition specified in this part or any symbol, stamp, label or seal indicating that the product has been officially graded and/or indicating the class, grade, quality, size, quantity, or condition of the product approved by the Administrator and authorized to be affixed to any product, or affixed to or printed on the packaging material of any product.

(e) "Official device" means a stamping appliance, branding device, stencil, printed label, or any other mechanically or manually operated tool that is approved by the Administrator for the purpose of applying any official mark or other identification to any product or the packaging material thereof.

6. Change § 56.4(c) to read:

§ 56.4 Basis of grading service.

* * * * *

(c) Whenever grading service is performed on a representative sample basis, such sample shall be drawn and consist of not less than the minimum number of cases as indicated in the following table. A minimum of one hundred eggs shall be examined per sample case. For lots which consist of less than 1 case, a minimum of 50 eggs shall be examined. If the lot consists of less than 50 eggs, all eggs will be examined.

MINIMUM NUMBER OF CASES COMPRISING A REPRESENTATIVE SAMPLE

Cases in lot:	*Cases in sample*
1 case	1
2 to 10, inclusive	2
11 to 25, inclusive	3
26 to 50, inclusive	4
51 to 100, inclusive	5
101 to 200, inclusive	8
201 to 300, inclusive	11
301 to 400, inclusive	13
401 to 500, inclusive	14
501 to 600, inclusive	16

For each additional 50 cases, or fraction thereof, in excess of 600 cases, one additional case shall be included in the sample.

7. Change § 56.6 to read:

§ 56.6 Supervision.

All grading service shall be subject to supervision at all times by the applicable State supervisor, circuit supervisor, area supervisor, and national supervisor. Such service shall be rendered where the facilities and conditions are satisfactory for the conduct of the service and the requisite graders and samplers are available. Whenever the supervisor of a grader has evidence that such grader incorrectly graded a product, such supervisor shall take such action as is necessary to correct the grading and to cause any improper grade marks which appear on the product or the containers thereof to be corrected prior to shipment of the product from the place of initial grading.

8. Change heading above § 56.10 to read: "Licensed Graders, Samplers, and Supervisors of Packaging"

9. Change § 56.10(c) to read:

§ 56.10 Who may be licensed.

* * * * *

(c) No person may be licensed to grade or sample any product in which he is financially interested.

10. Change § 56.11 to read:

§ 56.11 Limited license may be issued.

To any person possessing proper qualifications, as determined by the Administrator, there may be issued a limited license by the Secretary to candle and grade eggs on the basis of the "United States Standards for Quality of Individual Shell Eggs," with respect to eggs purchased from producers or eggs to be packaged with official identification. In addition, a limited license may be issued to any qualified person to act as a "supervisor of packing" in the packaging and grade labeling of products. No person to whom a limited license is issued by the Secretary shall have the authority to issue any grading certificate; and all eggs which are graded by any such person shall thereafter be check-graded by a grader. All limited licenses, issued by the Secretary, are to be countersigned by the officer in charge of the poultry grading service of the Agricultural Marketing Service or by any other official of such service designated by such officer.

11. Change § 56.13, § 56.15 and § 56.16 to read:

§ 56.13 Cancellation of license.

Upon termination of his services as a grader, sampler, or supervisor of packaging, each licensee and limited licensee shall surrender his license immediately for cancellation.

* * * * *

§ 56.15 Political activity.

All graders and samplers are forbidden during the period of their respective appointments or licenses, to take an active part in political management or in political campaigns. Political activities in city, county, State, or national elections, whether primary or regular, or in behalf of any party or candidate, or any measure to be voted upon, is prohibited. This applies to all appointees, including, but not being limited to, temporary and cooperative employees, and employees on leave of absence with or without pay. Willful violation of this section will constitute grounds for dismissal in the case of appointees and revocation of licenses in the case of licensees.

§ 56.16 Identification.

All graders, samplers, supervisors of packaging, and persons holding limited licenses shall each have in possession at all times, and present upon request, while on duty, the means of identification furnished by the Department to such person.

12. Change heading above § 56.20 to read: "Application for Grading and Sampling"

13. Change § 56.20 through § 56.24 to read:

§ 56.20 Who may obtain grading and sampling service.

An application for grading or sampling service may be made by any interested person, including, but not being limited to, the United States, any State, county, municipality, or common carrier, and any authorized agent of the foregoing.

§ 56.21 How to make application for grading.

(a) *On a fee basis.* An application for any grading service may be made in any office of grading, or with any grader or sampler at or nearest the place where the service is desired. Such application for service may be made orally (in person or by telephone), in writing, or by telegraph. If an application for grading service is made orally, the office of grading, grader or sampler with whom such application is made or the Administrator, may require that the application be confirmed in writing.

(b) *On a resident grading basis.* An application for continuous grading service on a resident grading basis to be rendered in an official plant must be made in writing on forms approved by the Administrator and filed with the Administrator.

§ 56.22 Filing of application.

An application for grading or sampling of a specified lot of any product shall be regarded as filed only when made pursuant to this part.

§ 56.23 Form of application.

Each application for grading or sampling a specified lot of any product shall include such information as may be required by the Administrator in regard to the product and the premises where such product is to be graded or sampled.

§ 56.24 When application may be rejected.

An application for grading service or sampling service may be rejected by the Administrator (a) whenever the applicant fails to meet the requirements of the regulations prescribing the conditions under which the service is made available; (b) whenever the product is owned by or located on the premises of a person currently denied the benefits of the act; (c) where any individual holding office or a responsible position with or having a substantial financial interest or share in the applicant is currently denied the benefits of the act or was responsible in whole or in part for the current denial of the benefits of the act to

any person; (d) where the Administrator determines that the application is an attempt on the part of a person currently denied the benefits of the act to obtain grading services; (e) whenever the applicant fails to bring the plant facilities, and operating procedures into compliance with the regulations within a reasonable period of time; (f) notwithstanding any prior approval whenever, before inauguration of service, the applicant fails to fulfill commitments concerning the inauguration of the service; (g) when it appears that to perform the services specified in this part would not be to the best interests of the public welfare or of the Government; or (h) when it appears to the Administrator that prior commitments of the Department necessitate rejection of the application. Each such applicant shall be promptly notified by registered mail of the reasons for the rejection. A written petition for reconsideration of such rejection may be filed by the applicant with the Administrator if postmarked or delivered within 10 days after the receipt of notice of the rejection. Such petition shall state specifically the errors alleged to have been made by the Administrator in rejecting the application. Within 20 days following the receipt of such a petition for reconsideration, the Administrator shall approve the application or notify the applicant by registered mail of the reasons for the rejection thereof.

14. Change § 56.30 to read:

§ 56.30 Report of violations.

Each grader, sampler and supervisor of packaging shall report in the manner prescribed by the Administrator, all violations and noncompliances under the act and this part of which such grader, sampler or supervisor of packaging has knowledge.

15. Change § 56.31(a) (1), (4) and (6) to read:

§ 56.31 Denial of service.

(a) * * *

(1) *Misrepresentation, deceptive, or fraudulent act or practice.* * * *

(i) The making or filing of an application for any grading service or sampling service, appeal or grading service;

(ii) The making of the product accessible for sampling or grading;

(iii) The making, issuing or using or attempting to issue or use any grading certificate, symbol, stamp, label, seal, or identification authorized pursuant to the regulations in this part;

(iv) The use of the terms "United States" or "U.S." in conjunction with the grade of the product;

(v) The use of any of the aforesaid terms or any official stamp, symbol, label, seal, or identification in the labeling or advertising of any product; or

(vi) The use of the terms "Government Grader," "Federal-State Graded," or terms of similar import in the labeling or advertising of any product.

* * * * *

(4) *Interfering with a grader or employee of the Service.* Any interference with or obstruction or any attempted interference or obstruction of or assault upon any grader, licensee, or employee of the Service in the performance of his duties. The giving or offering, directly or indirectly, of any money, loan, gift, or anything of value to an employee of the Service or the making or offering of any contribution to or in any way supplementing the salary, compensation or expenses of an employee of the Service or the offering or entering into a private contract or agreement with an employee of the Service for any services to be rendered while employed by the Service.

* * * * *

(6) *Miscellaneous.* The existence of any of the conditions set forth in § 56.24 constituting the basis for the rejection of an application for grading service.

* * * * *

16. Delete §§ 56.35 through 56.43 and add new §§ 56.35 to 56.41 to read:

§ 56.35 Authority to use, and approval of official identification.

(a) *Authority to use official identification.* Authority to officially identify product, graded pursuant to this part, is granted only to applicants who make the services of a grader or supervisor of packaging available for use in accordance with this part. Packaging materials bearing official identification marks shall be approved pursuant to §§ 56.35 to 56.39, both inclusive, and shall be used only for the purpose for which approved and shall not otherwise be disposed of from the plant for which approved except with written approval of the Administrator. Any unauthorized use or disposition of approved labels or packaging material which bears any official identification may result in cancellation of the approval and denial of the use of labels or packaging material bearing official identification or denial of the benefits of the Act pursuant to the provisions of § 56.31.

(b) *Approval of official identification.* Any label or packaging material which bears any official identification shall be used only in such manner as the Administrator may prescribe. No label or packaging material bearing official identification may be used unless finished copies or samples of such labels and packaging material have been approved by the Administrator, except that a grader may apply official identification stamps to shipping containers if they do not bear any statement that is false or misleading. No label bearing the official identification shall be printed for use until the printer's final proof has been approved by the Administrator; and no label bearing any official identification shall be used until finished copies or samples of such label have been approved by the Administrator. A label which bears official identification shall not bear any statement that is false or misleading. If the label is printed or otherwise applied directly to the container, the principal display panels of such container shall for this purpose be considered as the label. The label shall contain the name and address of the packer or distributor of the product, the name of the product and a statement of the net contents of the container.

§ 56.36 Information required on, and form of grade mark.

(a) *Information required on grade mark.* Except as otherwise authorized, each grade mark provided for in this section shall conspicuously and legibly indicate: (1) The letters "USDA"; (2) the U.S. Grade of the product it identifies, such as, "U.S. A Grade"; (3) one of the following phrases: "Graded under Federal-State Supervision," "Graded under U.S. and State Supervision," or a term of similar import; (4) the size or weight class of the product, such as "Large," except that the size may be omitted from the grade mark if it appears prominently on the main panel of the carton; (5) the plant number of the official plant where the product was packed, except that the appropriate plant number may be shown legibly elsewhere on the packaging material.

(b) *Form of official identification symbol and grade mark.* (1) The shield set forth in Figure 1 shall be the official identification symbol for purposes of this part, and when used, imitated, or simulated in any manner in connection with shell eggs shall be deemed to constitute a representation that the product has been officially graded for the purposes of § 56.2.

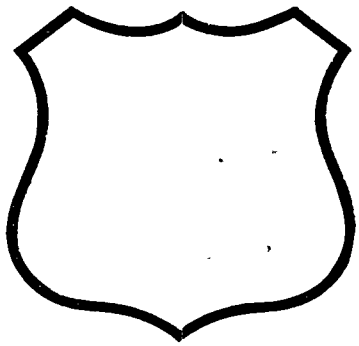

FIGURE 1.

(2) Except as otherwise authorized, the grade mark permitted to be used to officially identify cartons of shell eggs which are graded pursuant to the regulations in this part shall be contained in a shield and in the form and design indicated in Figures 2 and 3 of this section. The shield shall be of sufficient size so that the print and other information contained therein is distinctly legible and in approximately the same proportion and size as shown in Figures 2 and 3. When the size or weight class is included as a part of the grade mark, the form of such mark shall be as indicated in Figure 2 and when the size or weight class is not included in the grade mark the form of such mark shall be as indicated in Figure 3. The grade mark shall be printed on the carton or on a tape used to seal the carton.

FIGURE 2.

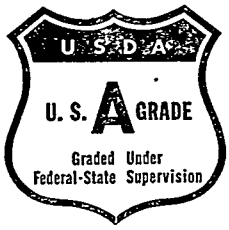

FIGURE 3.

(3) *Fresh Fancy Quality or AA grade mark.* Eggs which are packaged pursuant to § 56.42 and are to be grade marked shall be labeled with one of the following grade marks:

FIGURE 4.

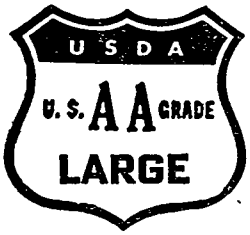

FIGURE 5.

FIGURE 6.

(4) *Alternate Grade A mark.* Eggs which are packaged pursuant to § 56.43 and are to be grade marked shall be labeled with the grade mark shown in Figures 2 and 3 of subparagraph (2) of this paragraph, or with the following grade mark:

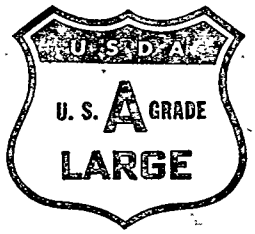

FIGURE 7.

§ 56.37 Dating of officially identified product.

Each carton identified with grade marks shown in § 56.36, other than those shown in Figures 4 and 5 of paragraph (b) (3) and Figure 7 of paragraph (b) (4) of § 56.36, shall have either the date the eggs were graded or an expiration date applied legibly to the carton or on the tape used to seal the carton in a manner satisfactory to the Administrator.

(a) If the date of grading is used, it shall be expressed as the "month" and "day," or the number of the "month" and "day," or as the consecutive day of the year, except that the Administrator may prohibit the use of the consecutive day of the year when it is demonstrated that marketing practices of a firm are such that the original quality of the eggs identified is not adequately protected.

(b) If the expiration date is used, it shall be stated as the month and day or the number of the month and day preceded by the letters "Exp." or a statement such as, "Not to be sold after." The expiration date shall not exceed 10 days from the date of grading, excluding date of grading.

§ 56.38 Rescindment of approved labels.

Once a year, or more often, if requested, each applicant shall submit to the Administrator a list, in triplicate, of approved labels which bear any official identification that have become obsolete, accompanied with a statement that such approvals are no longer desired. The approvals shall be identified by the date of approval, and the grade, weight class, and brand name of the product.

PREREQUISITES TO PACKAGING PRODUCTS IN CARTONS WITH GRADE IDENTIFICATION LABELS

§ 56.39 Supervisor of packaging required.

The official identification of any graded product as provided in §§ 56.35 to 56.43, inclusive, shall be done only under the supervision of a grader or supervisor of packaging. The grader or supervisor of packaging shall have supervision over the use and handling of all material bearing any official identification.

§ 56.40 Grading requirements of shell eggs for packaging with grade identification labels.

Shell eggs shall not be packaged with any grade identification label unless such eggs are first individually graded (a) by a grader, or (b) by a limited licensee, pursuant to § 56.11 and thereafter check-graded by a grader.

§ 56.41 Limitations applicable to grade marking consumer packages of A and AA grade or Fresh Fancy Quality eggs.

Eggs which are to be grade marked as U.S. A and AA grade or Fresh Fancy Quality and packed in consumer packages shall be packed from eggs of current production. Eggs known to possess undesirable odors and flavors shall not be officially identified as U.S. Grade A, AA or Fresh Fancy Quality.

17. Renumber § 56.44 to read § 56.42.

18. Change § 56.42(a) (5) and (b) (1), (2), (3), (4), (5), (8), (9) and (10) to read:

§ 56.42 Requirements for eggs packaged under Fresh Fancy Quality grade mark or AA grade mark as shown in Figures 4, 5, and 6 of § 56.36.

(a) *Minimum requirements of procurement and distribution program.* Each packing station or plant must have a satisfactory procurement and distribution program including, but not being limited to, the following requirements at the farm and retail store level as applicable:

* * * * *

(5) Eggs shall be transported and handled under such conditions as will prevent sweating and at a temperature of 60° F. or below.

* * * * *

(b) *Minimum requirements at packaging plant.* (1) The quality factor of albumen firmness shall be determined by the broken-out score, measured in Haugh units, and the condition of the yolk shall be observed during such testing. The break-out test shall be made weekly and shall be accomplished at the assembly plant or at the farm in the event the eggs go directly from the farm to the store. Eggs that do not meet the requirements of AA quality with respect to shell texture or shape shall not be selected as part of any sample that is to be broken-out and scored. Sampling, break-out testing, and maintenance of records of break-out tests shall be done by or under the immediate supervision of a grader.

(2) The internal temperature of the eggs shall not be lower than 45° F. or higher than 60° F. at the time of making the break-out test. Eggs shall be placed under refrigeration at a temperature not to exceed 60° F. immediately after packaging.

(3) A flock may be eligible for entry under the program when a sample of 25 eggs drawn at random averages 76 Haugh units or higher; or when two samples of 25 eggs each drawn at random (one sample per week for two consecutive weeks) each averages 74 Haugh units or higher. Notwithstanding the

foregoing, a flock shall not be eligible if any sample contains more than one egg measuring less than 60 Haugh units, and the yolk of all eggs in the sample shall have a well-rounded appearance with a reasonably uniform color.

(4) A flock may remain on the program: *Provided,* That (i) a moving average of 74 Haugh units or higher is maintained; (ii) that the yolks of all eggs have a well-rounded appearance with a reasonably uniform color; and (iii) that not more than one egg in any sample of 10 eggs or more measures less than 60 Haugh units.

(5) The weekly average shall be computed by averaging the results obtained when testing eggs in accordance with either subdivision (i) or (ii) of this subparagraph. Samples shall be drawn at random once a week per flock from a single shipment, and the yolk of all eggs in the sample shall have a well-rounded appearance with a reasonably uniform color.

(i) A sample of 10 eggs shall be tested when the moving average is below 80 Haugh units and not more than one egg in the sample shall measure less than 60 Haugh units.

(ii) A sample of 5 eggs shall be tested when the moving average is 80 Haugh units or above and the sample shall contain no eggs which measure less than 60 Haugh units. If only one egg measures less than 60 Haugh units, an additional 5 eggs shall be tested. If this second 5-egg sample contains no eggs below 60 Haugh units, the average of the 10 eggs shall be used in determining the weekly average.

* * * * *

(8) Eggs with clean, unbroken, practically normal shells from flocks which meet the provisions of this section may be packaged and officially labeled as Fresh Fancy Quality or U.S. Consumer Grade AA after the removal of eggs containing blood and meat spots and loss eggs.

(9) Packages or sealing tapes shall bear in distinctly legible form a date, stated as the month and day or the number of the month and day, preceded by the letters "Exp." or a statement such as "Not to be sold after." The date shall not exceed 10 days from the date of Haugh unit test, excluding day of testing, except that the expiration date may be established by starting with the date of packing for shipments received during the interim between the weekly Haugh unit test, provided such eggs are packed prior to the next weekly test. Upon expiration of the 10 days, the eggs shall be removed from the labeled packages or the official grade mark shall be completely obliterated. Notwithstanding the foregoing, the Administrator may approve other systems of dating which accomplish the purposes of the paragraph, provided application for such a system is made in writing by the applicant and concurred in by the Administrator.

(10) Graders shall examine samples of packaged product in accordance with the provisions of § 56.4. A tolerance of 5 percent is permitted in any combination of eggs that are of B quality or C quality with respect to shell, meat or blood spots, and checks. Dirties, Leakers and Loss are not permitted.

19. Renumber § 56.44a to read § 56.43 and change to read:

§ 56.43 Requirements for eggs packaged under the U.S. Grade A mark as shown in Figure 7 of § 56.36.

Eggs packaged with the grade label designation specified in Figure 7 of § 56.36 shall meet all of the provisions of § 56.42 except for the following:

(a) A flock shall consist of birds located on the same farm and managed under identical supervision.

(b) A flock may be eligible for entry under the program when a sample of 25 eggs drawn at random averages 64 Haugh units or higher; or when two samples of 25 eggs each drawn at random (one sample per week for two consecutive weeks) each averages 62 Haugh units or higher. Notwithstanding the foregoing, a flock shall not be eligible if any sample contains more than four eggs measuring less than 60 Haugh units, and the yolk of all eggs in the sample shall have a well-rounded appearance with a reasonably uniform color.

(c) A flock may remain on the program: *Provided,* That (1) a moving average of 62 Haugh units or higher is maintained; (2) the yolks of all eggs have a well-rounded appearance with a reasonably uniform color; and (3) not more than two eggs in any sample of 10 eggs measure less than 60 Haugh units.

(d) The weekly average shall be computed by averaging the results obtained by testing 10 eggs per flock per week. Samples shall be drawn at random once a week. Notwithstanding the foregoing, 5 eggs may be used as the sample size when the moving average is such that the flock would qualify under the provisions of § 56.42.

20. Change § 56.45(a) to read:

§ 56.45 Payment for fees and charges.

(a) Fees and charges for any grading service shall be paid by the interested party making the application for such grading service, in accordance with the applicable provisions of this section and §§ 56.46 to 56.54, both inclusive; and, if so required by the grader or sampler, such fees and charges shall be paid in advance.

* * * * *

21. Change § 56.46(b) to read:

§ 56.46 On a fee basis.

(b) In the event the aforesaid applicable rates are deemed by the Administrator to be inadequate fully to reimburse the Service for all costs and other items paid or incurred by the Service in connection with such service, the fees for such service shall not be based on the rates specified in § 56.50, but shall be based on the time required to perform such service and the travel of each sampler, grader and supervisor of packaging at the rate of $5.60 per hour for the time actually required.

* * * * *

22. Change § 56.51 to read:

§ 56.51 Additional charges.

With respect to any grading service performed in a freight or express car or any other place where the entire lot of the product is not readily accessible to the grader or sampler, if the time required for the performance of such service is greater than would otherwise be required if the entire lot were readily accessible, as aforesaid, a fee of $5.60 shall be charged in addition to the applicable rates specified in § 56.50.

23. Change § 56.52(a) (1) and (6) to read, and add § 56.54:

§ 56.52 On a resident grading basis.

(a) *Charges.* * * *

(1) A charge of $5.60 per hour plus actual costs to AMS for per diem and travel costs incurred in rendering service not specifically covered in this section; such as, but not limited to initial surveys;

* * * * *

(6) A charge to cover the actual cost to AMS of the travel (including the cost of movement of household goods and dependents) and per diem with respect to each grader who is transferred (other than for the convenience of AMS) from an official station to the designated plant;

* * * * *

§ 56.54 Charges for continuous grading service on a non-resident basis.

When grading service is furnished on a continuous non-resident basis, the charges and other provisions contained in § 56.52 are applicable with the exception of § 56.52(a) (1) and (9). The administrative charge shall be computed by adding 20 percent to each of the charges specified in § 56.52(a) (3) and (7).

24. Change § 56.62 to read:

§ 56.62 How to obtain appeal grading.

Appeal grading may be obtained by filing a request therefor (a) with the Administrator, (b) with the grader who issued the grading certificate with respect to which the appeal grading is requested, (c) with the immediate superior of such grader, or (d) with the officer in charge of any office of grading. The application for appeal grading shall state the reasons therefor and may be accompanied by a copy of the aforesaid grading certificate or any other information the applicant may have secured regarding the product, at the time of grading, from which the appeal is requested. Such application may be made orally (in person or by telephone), in writing, or by telegraph. If made orally, written confirmation may be required.

25. Change § 56.75 to read:

§ 56.75 Applicability of facility and operating requirements.

The provisions of § 56.76 shall be applicable to any grading service that is provided on a resident basis.

26. Change § 56.76(b) (3), (c) (1), and (f) (1) to read:

§ 56.76 Minimum facility and operating requirements for shell egg grading and packing plants.

* * * * *

(b) *Grading room requirements.* * * *

(3) The candling lights shall be capable of delivering reasonably uniform intensity of light at the candling aperture to facilitate accurate quality determinations; and the light shall provide ample case light for detection of stained and dirty shells and the condition of the packing materials. In operations utilizing mechanical grading equipment, adequate light shall be provided to facilitate necessary quality determinations, including the detection and removal of stained and dirty shells and the condition of the packing material.

* * * * *

(c) *Cooler room requirements.* (1) Cooler rooms shall have refrigeration facilities capable of reducing within 24 hours and holding the maximum volume of eggs handled to 60° F. or below.

* * * * *

(f) *Requirements for eggs to be officially grade marked.* (1) Shell eggs, except as otherwise provided for in §§ 56.42 and 56.43, which are to bear the official grade mark shall meet the following temperature requirements: Eggs shall not be below 45° F. or above 70° F. at the time of official grading. Eggs held in the plant shall be placed under refrigeration of 60° F. or below immediately after packaging.

* * * * *

27. Change first paragraph of § 56.100 to read:

§ 56.100 Application for grading service with respect to shell eggs.

Application is hereby made, in accordance with the applicable provisions of the regulations (7 CFR Part 56) governing the grading of shell eggs and United States standards, grades and weight classes for shell eggs, for shell egg grading service at the following designated plant:

* * * * *

28. Change § 56.200 (a) and (b) to read:

§ 56.200 Application.

(a) The United States standards for quality of individual shell eggs contained in this subpart are applicable only to eggs that are the product of the domesticated chicken hen and are in the shell.

(b) Interior egg quality specifications for these standards are based on the apparent condition of the interior contents of the egg as it is twirled before the candling light, except as otherwise provided in § 56.42 or § 56.43. Any type or make of candling light may be used that will enable the particular grader to make consistently accurate determination of the interior quality of shell eggs. It is desirable to break out an occasional egg and by determining the Haugh unit value of the broken-out egg, compare the broken-out and candled appearance, thereby aiding in correlating candled and broken-out appearance.

29. Change § 56.201 to read:

§ 56.201 AA Quality.

The shell must be clean, unbroken, and practically normal. The air cell must not exceed ⅛-inch in depth and be practically regular. The white must be clear and firm so that the yolk is only slightly defined when the egg is twirled before the candling light. The yolk must be practically free from apparent defects.

30. Change § 56.202 to read:

§ 56.202 A Quality.

The shell must be clean, unbroken, and practically normal. The air cell must not exceed 3/16 inch in depth and must be practically regular. The white must be clear and at least reasonably firm so that the yolk outline is only fairly well defined when the egg is twirled before the candling light. The yolk must be practically free from apparent defects.

31. Change § 56.203 to read:

§ 56.203 B Quality.

The shell must be unbroken and may be slightly abnormal and may show slight stains but no adhering dirt: *Provided,* That they do not appreciably detract from the appearance of the egg. When the stain is localized, approximately 1/32 of the shell surface may be slightly stained, and when the slightly stained areas are scattered, approximately 1/16 of the shell surface may be slightly stained. The air cell must not exceed ⅜ inch in depth, may show unlimited movement, and may be free or bubbly. The white must be clear and may be slightly weak so that the yolk outline is well defined when the egg is twirled before the candling light. The yolk may appear slightly enlarged or slightly flattened and may show other definite, but not serious, defects.

32. Change § 56.204 to read:

§ 56.204 C Quality.

The shell must be unbroken, may be abnormal and may have slightly stained areas. Moderately stained areas are permitted if they do not cover more than ¼ of the shell surface. Eggs having shells with prominent stains or adhering dirt are not permitted. The air cell may be over ⅜ inch in depth and may be free or bubbly. The white may be weak or watery so that the yolk outline is plainly visible when the egg is twirled before the candling light. The yolk may appear dark, enlarged, and flattened, and may show clearly visible germ development but no blood due to such development. It may show other serious defects that do not render the egg inedible. Small blood clots or spots (aggregating not more than ⅛ inch in diameter) may be present.

33. Change § 56.205 to read:

§ 56.205 Dirty.

The shell must be unbroken and it has adhering dirt, prominent stains, or moderate stains covering more than ¼ of the shell surface.

34. Change § 56.208(b) to read:

§ 56.208 Terms descriptive of the shell.

* * * * *

(b) *Dirty.* A shell which has dirt adhering to its surface or which has prominent stains or moderate stains covering more than ¼ of the shell surface.

* * * * *

35. Change § 56.210 (b), (c), (d), and (e) to read:

§ 56.210 Terms descriptive of the white.

* * * * *

(b) *Firm.* A white that is sufficiently thick or viscous to prevent the yolk outline from being more than slightly defined or indistinctly indicated when the egg is twirled. With respect to a broken-out egg, a firm white has a Haugh unit value of 72 or higher when measured at a temperature between 45° and 60° F.

(c) *Reasonably firm.* A white that is somewhat less thick or viscous than a firm white. A reasonably firm white permits the yolk to approach the shell more closely which results in a fairly well defined yolk outline when the egg is twirled. With respect to a broken-out egg, a reasonably firm white has a Haugh unit value of 60 to 72 when measured at a temperature between 45° and 60° F.

(d) *Slightly weak.* A white that is lacking in thickness or viscosity to an extent that causes the yolk outline to appear well defined when the egg is twirled. With respect to a broken-out egg, a slightly weak white has a Haugh unit value of 31 to 60 when measured at a temperature between 45° and 60° F.

(e) *Weak and watery.* A white that is thin and generally lacking in viscosity. A weak and watery white permits the yolk to approach the shell closely, thus causing the yolk outline to appear plainly visible and dark when the egg is twirled. With respect to a broken-out egg, a weak and watery white has a Haugh unit value lower than 31 when measured at a temperature between 45° and 60° F.

36. Delete § 56.211 (a), (b) and (c) and renumber paragraphs (d) through (o) to read (a) through (l).

37. Change heading above § 56.215 to read: "United States Grades and Weight Classes for Shell Eggs."

38. Change § 56.215 (a), (c) and (e) to read:

§ 56.215 General.

(a) These grades are applicable to edible shell eggs in "lot" quantities rather than on an "individual" egg basis. A lot may contain any quantity of two or more eggs. Reference in these standards to the term "case" means 30-dozen egg cases as used in commercial practices in the United States. The size of the sample used to determine grade shall be on the basis of the requirements of § 56.4.

* * * * *

(c) An aggregate tolerance of 20 percent is permitted within each consumer grade only as an allowance for variable efficiency and interpretation of graders, normal changes under favorable condi-

tions during reasonable periods between grading, and reasonable variation of grader's interpretation.

* * * * *

(e) The percentage requirements for grades as set forth in §§ 56.216 and 56.217 are applicable except that interior quality factors shall be determined in accordance with the requirements of § 56.42 or § 56.43 when the lot is labeled "Produced and Marketed under Federal-State Quality Control Program."

39. Add a new paragraph (f) to § 56.215 to read:

(f) "No grade" means eggs of possible edible quality that fail to meet the requirements of an official U.S. Grade or that have been contaminated by smoke, chemicals, or other foreign material which has seriously affected the character, appearance, or flavor of the eggs.

40. Add a new heading above § 56.216 to read: "United States Consumer Grades and Weight Classes for Shell Eggs".

41. Delete paragraphs (e) and (g) of § 56.216.

42. Renumber paragraph (f) of § 56.216 to read paragraph (e) and change § 56.216 (a), (b), (c) and (e) to read:

§ 56.216 Grades.

(a) Fresh Fancy Quality shall consist of eggs meeting the requirements as set forth in § 56.42.

(b) "U.S. Consumer Grade AA" shall consist of eggs of which at least 80 percent are AA quality. Within the maximum tolerance of 20 percent, which may be below AA quality, not more than 5 percent may be of the qualities below A, in any combination, but not including Dirties and Leakers. This grade name is also applicable when the lot consists of eggs meeting the requirements as set forth in § 56.42.

(c) "U.S. Consumer Grade A" shall consist of eggs of which at least 80 percent are A quality or better. Within the maximum tolerance of 20 percent which may be below A quality, not more than 5 percent may be of the qualities below B, in any combination but not including Dirties and Leakers. This grade name is also applicable when the lot consists of eggs meeting the requirements as set forth in § 56.43.

* * * * *

(e) *Additional tolerances.* (1) Within the maximum tolerances permitted, an allowance will be made at receiving points or shipping destination for ½ percent Leakers in Fresh Fancy Quality and U.S. Consumer Grades AA, A, and B.

(2) In lots of two or more cases, no individual case may fall below 70 percent of the specified quality and no individual case may contain less than 90 percent (80 percent for Grade B) of the specified quality and the next lower quality. The remaining 10 percent (20 percent for Grade B) may consist of a combination of qualities below the next lower quality (i.e., in lots of Grade A, not more than 10 percent of the qualities in individual cases within the sample may be C or Check, provided the average is not over 5 percent). In lots of 2 or more cartons, no individual carton may contain less than 8 eggs of the specified quality and no individual carton may contain less than 10 eggs of the specified quality and the next lower quality. The remaining 2 eggs may consist of a combination of qualities below the next lower quality (i.e., in lots of Grade A, not more than 2 eggs of the qualities in individual cartons within the sample may be C or Check).

43. Change § 56.217 to read:

§ 56.217 Summary of grades.

The summary of U.S. Consumer Grades for Shell Eggs follows as Table I and Table II of this section:

TABLE I—SUMMARY OF U.S. CONSUMER GRADES FOR SHELL EGGS

U.S. consumer grade	At least 80 percent (lot average) [1] must be—	Tolerance permitted [2]	
		Percent	Quality
Grade AA or Fresh Fancy Quality	AA Quality	15 to 20 Not over 5 [3]	A. B, C, or Check.
Grade A	A Quality or better.	15 to 20 Not over 5 [3]	B. C or Check.
Grade B	B Quality or better.	10 to 20 Not over 10 [3]	C. Dirty or Check.

[1] In lots of two or more cases or cartons, see table II of this section for tolerances for individual case or carton within a lot.
[2] Within tolerance permitted, an allowance will be made at receiving points or shipping destination for ½ percent leakers in Grades AA, A, and B.
[3] Substitution of higher qualities for the lower qualities specified is permitted.

TABLE II—TOLERANCE FOR INDIVIDUAL CASE OR CARTON WITHIN A LOT

U.S. consumer grade	Case—minimum quality—percent [1]	Carton—minimum quality—number eggs [1]
Grade AA or Fresh Fancy Quality.	70% AA 20% A 10% B, C or Check.	8 eggs AA. 2 eggs A. 2 eggs B, C or Check.
Grade A	70% A 20% B 10% C or Check.	8 eggs A. 2 eggs B. 2 eggs C or Check.
Grade B	70% B 10% C 20% Check or Dirty.	8 eggs B. 2 eggs C. 2 eggs Check or Dirty.

[1] Substitution of higher qualities for lower qualities specified is permitted.

44. Delete § 56.220.

45. Delete § 56.225.

46. Delete § 56.226(g).

47. Delete § 56.230.

48. Change § 56.234(a) to read:

§ 56.234 Packaging material.

(a) Eggs graded and labeled as an export grade shall be packed in new standard cases and new standard packing material. New standard wood cases shall comply with the requirements of paragraph 5.2.1.2 of Federal Specification C-E 271d "Eggs Shell," dated November 12, 1959. New standard fiber cases shall be of one of the following types:

* * * * *

(60 Stat. 1090, as amended; 7 U.S.C. 1624)

Done at Washington, D.C. this 17th day of June 1963, to become effective August 1, 1963.

G. R. GRANGE,
Deputy Administrator,
Marketing Services.

[F.R. Doc. 63-6511; Filed, June 19, 1963; 8:57 a.m.]

Chapter IX—Agricultural Marketing Service (Marketing Agreements and Orders; Fruits, Vegetables, Tree Nuts), Department of Agriculture

[Elberta Peach Reg. 1]

PART 917—FRESH BARTLETT PEARS, PLUMS, AND ELBERTA PEACHES GROWN IN CALIFORNIA

Regulation by Grades and Sizes

§ 917.324 Elberta Peach Regulation 1.

(a) *Findings.* (1) Pursuant to the marketing agreement, as amended, and Order No. 917, as amended (7 CFR Part 917), regulating the handling of fresh Bartlett pears, plums, and Elberta peaches grown in the State of California, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and upon the basis of the recommendations of the Elberta Peach Commodity Committee, established under the aforesaid amended marketing agreement and order, and upon other available information, it is hereby found that the limitation of shipments of Elberta peaches, as hereinafter provided, will tend to effectuate the declared policy of the act.

(2) It is hereby further found that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice, engage in public rule-making procedure, and postpone the effective date of this section until 30 days after publication thereof in the FEDERAL REGISTER (5 U.S.C. 1001–1011) in that, as hereinafter set forth, the time intervening between the date when information upon which this section is based became available and the time when this section must become effective in order to effectuate the declared policy of the act is insufficient; a reasonable time is permitted, under the circumstances, for preparation for such effective time; and good cause exists for making the provision hereof effective not later than June 21, 1963. A reasonable determination as to the supply of, and the demand for, such peaches must await the development of the crop and adequate information thereon was not available to the Elberta Peach Commodity Committee until May 23, 1963; recommendation as to the need for, and the extent of, regulation of shipments of such peaches was made at the meeting of said committee on May 23, 1963, after consideration of all available information relative to the supply and demand conditions for such peaches, at which time the recommendation and supporting information were submitted to the Department; necessary supplemental data for consideration in

connection with the specifications of the provisions were not available until June 14, 1963; shipments of the current crop of such peaches are expected to begin on or about June 21, 1963, and this section should be applicable to all shipments of such peaches in order to effectuate the declared policy of the act; and compliance with the provisions of this section will not require of handlers any preparation therefor which cannot be completed by the effective time hereof.

(b) *Order.* (1) During the period beginning at 12:01 a.m., P.s.t., June 21, 1963, and ending at 12:01 a.m., P.s.t., November 2, 1963, no shipper shall ship:

(i) Any package or container of Elberta peaches unless such peaches meet the requirements of the U.S. No. 1 grade: *Provided,* That with respect to ripe Elberta peaches, a tolerance of 10 percent, by count, for bruises not causing serious damage is allowed in addition to the tolerances provided for such U.S. No. 1 grade;

(ii) Any package or container of Elberta peaches unless at least 85 percent, by count, of such peaches are well matured (as such term is defined in subparagraph (2) of this paragraph);

(iii) Any lot of packages or containers of Elberta peaches if more than three (3) percent, by count, of the peaches in such lot are immature;

(iv) Any package or container of Elberta peaches unless at least 85 percent of the Elberta peaches contained in such package or container measure not less than 2⅜ inches in diameter: *Provided,* That, Elberta peaches (*a*) when packed in a 12B California peach box, which are of the size that will pack, in accordance with the requirements prescribed for a standard pack, 65 peaches in said box, or (*b*) when packed in either a No. 26 standard lug box or a No. 27 standard lug box, which are of the size that will pack, in accordance with the requirements prescribed for a standard pack, not more than 80 peaches in the respective lug box, shall be deemed to meet the said minimum diameter requirement: *And provided, further,* That for the purpose of determining whether ripe Elberta peaches meet the said standard pack requirements, such peaches may be fairly tightly packed rather than tightly packed.

(2) Peaches which are "well matured" means peaches which, at the time of picking, (i) have shoulders and sutures well filled out and smooth; (ii) have skin which is at least very light green to yellowish green in color; (iii) have flesh that is yellow or straw color with only a small portion usually next to the skin being greenish yellow or greenish straw color; (iv) have flesh which shows some juiciness; and (v) yield very slightly to moderate pressure at the suture or tip.

(3) Section 917.143 sets forth the requirements with respect to the inspection and certification of shipments of Elberta peaches. Such section also prescribes the conditions which must be met if any shipment is to be made without prior inspection and certification. Notwithstanding that shipments may be made without inspection and certification, each shipper shall comply with all grade and size regulations applicable to the respective shipment.

(4) Terms used in the amended marketing agreement and order shall, when used herein, have the same meaning as given to the respective term in said amended marketing agreement and order; "U.S. No. 1," "bruises," "defects," "damage," "serious damage," "standard pack," "tightly packed," and "fairly tightly packed" shall have the same meaning as when used in the United States Standards for Peaches (§§ 51.1210 to 51.1223 of this title); "No. 26 standard lug box" and "No. 27 standard lug box," respectively, shall have the same meaning as set forth in section 828.4 of the Agricultural Code of California; "No. 12B California peach box" shall have the same meaning as set forth in section 828.25 of the Agricultural Code of California; and "diameter" shall mean the distance through the widest portion of the cross section of a peach at right angles to a line running from the stem to the blossom end.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: June 17, 1963.

PAUL A. NICHOLSON,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[F.R. Doc. 63-6510; Filed, June 19, 1963; 8:57 a.m.]

Title 9—ANIMALS AND ANIMAL PRODUCTS

Chapter I—Agricultural Research Service, Department of Agriculture

SUBCHAPTER A—MEAT INSPECTION REGULATIONS

PART 18—REINSPECTION AND PREPARATION OF PRODUCTS

Addition of Products Required To Be Treated for the Destruction of Trichinae

On February 5, 1963, there was published in the FEDERAL REGISTER (28 F.R. 1115) a notice of proposed amendment of § 18.10(b) of the Federal Meat Inspection Regulations (9 CFR 18.10(b)), to include certain products in the list of products, at federally inspected establishments, specifically required by § 18.10 (b) to be effectively heated, refrigerated, or cured to destroy any possible live trichinae.

After due consideration of all relevant material in connection with such notice and under the authority of the Meat Inspection Act, as amended (21 U.S.C. 71–91) and sections 306 (b) and (c) of the Tariff Act of 1930, as amended (19 U.S.C. 1306 (b) and (c)), § 18.10(b) of the Meat Inspection Regulations (9 CFR 18.10 (b)) is hereby amended to read as follows:

(b) Products named in this paragraph, and products of the character thereof, containing pork muscle tissue (including hearts, pork stomachs and pork livers), or the pork muscle tissue which forms an ingredient of such products, shall be effectively heated, refrigerated, or cured at a federally inspected establishment to destroy any possible live trichinae: bologna; frankfurts; viennas; smoked sausage; knoblauch sausage; mortadella; all forms of summer or dried sausage, including mettwurst; ground meat mixtures containing pork and beef, veal, lamb, mutton or goat meat and prepared in such a manner that they might be eaten rare or without thorough cooking; flavored pork sausage such as those containing wine or similar flavoring materials; cured pork sausage; sausage containing cured and/or smoked pork; cooked loaves; roasted, baked, boiled, or cooked hams, pork shoulders, or pork shoulder picnics; Italian-style hams; Westphalia-style hams; smoked boneless pork shoulder butts; cured meat rolls; capocollo (capicola, capacola); coppa; fresh or cured boneless pork shoulder butts, hams, loins, shoulders, shoulder picnics, and similar pork cuts, in casings or other containers in which ready-to-eat delicatessen articles are customarily enclosed (excepting Scotch-style hams); breaded pork products; cured boneless pork loins; boneless back bacon; smoked pork cuts such as hams, shoulders, loins and pork shoulder picnics (excepting smoked hams and smoked pork shoulder picnics which are specially prepared for distribution in tropical climates or smoked hams delivered to the Armed Services). Cured boneless pork loins shall be subjected to prescribed treatment for destruction of trichinae prior to being shipped from the establishment where cured.

(34 Stat. 1264, 21 U.S.C. 89; Sec. 306, 46 Stat. 689, as amended; 19 F.R. 74, as amended)

The amendment shall become effective 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 17th day of June 1963.

M. R. CLARKSON,
Acting Administrator, Agricultural Research Service.

[F.R. Doc. 63-6507; Filed, June 19, 1963; 8:56 a.m.]

SUBCHAPTER C—INTERSTATE TRANSPORTATION OF ANIMALS AND POULTRY

PART 74—SCABIES IN SHEEP

Interstate Movement

Pursuant to the provisions of sections 1 through 4 of the Act of March 3, 1905, as amended, sections 1 and 2 of the Act of February 2, 1903, as amended, and sections 4 through 7 of the Act of May 29, 1884, as amended (21 U.S.C. 111–113, 115, 117, 120, 121, 123–126), §§ 74.2 and 74.3 of Part 74, Subchapter C, Chapter I, Title 9, Code of Federal Regulations, as amended, are hereby amended to read, respectively, as follows:

§ 74.2 Designation of free and infected areas.

(a) Notice is hereby given that sheep in the following States, territories, and

district, or parts thereof as specified, are not known to be infected with scabies, and such States, territories, district, and parts thereof, are hereby designated as free areas:

(1) Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Idaho, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Texas, Utah, Vermont, Washington, Wisconsin, and Wyoming;

(2) The following counties in Nebraska: Arthur, Banner, Blaine, Box Butte, Brown, Chase, Cherry, Cheyenne, Dawes, Deuel, Dundy, Garden, Grant, Hooker, Keith, Keya Paha, Kimball, Loup, Morrill, Perkins, Rock, Sheridan, Sioux, Scotts Bluff, and Thomas;

(3) The following counties in Hawaii: Honolulu, Kauai, and Maui;

(4) All counties in Mississippi except Bolivar and Washington;

(5) St. John and St. Thomas Islands of the Virgin Islands of the United States;

(6) The following counties in Missouri: Jackson, Lafayette, Saline, Cooper, Moniteau, Cole, Osage, Gasconade, Franklin, St. Louis, and all Counties in the State of Missouri lying south thereof.

(b) Notice is hereby given also that sheep scabies exists in all States and territories and parts of States not designated as free areas in paragraph (a) of this section, and they are hereby designated as infected areas.

§ 74.3 Designation of eradication areas.

(a) Notice is hereby given that sheep in the following States, territory, or parts thereof as specified, are being handled systematically to eradicate scabies in sheep, and such States, territory, and parts thereof, are hereby designated as eradication areas:

(1) Illinois, Kentucky, Tennessee, and Virginia;

(2) All counties in Nebraska except Arthur, Banner, Blaine, Box Butte, Brown, Chase, Cherry, Cheyenne, Dawes, Deuel, Dundy, Garden, Grant, Hooker, Keith, Keya Paha, Kimball, Loup, Morrill, Perkins, Rock, Sheridan, Sioux, Scotts Bluff, and Thomas;

(3) All counties in Hawaii except Honolulu, Kauai, and Maui;

(4) The following counties in Mississippi: Bolivar and Washington;

(5) The following counties in West Virginia: Berkeley, Fayette, Grant, Greenbrier, Hampshire, Hardy, Jefferson, Mercer, Mineral, Monroe, Morgan, Nicholas, Pendleton, Pocahontas, Raleigh, Randolph, Summers, Tucker, Upshur, and Webster;

(6) St. Croix Island of the Virgin Islands of the United States:

(7) All counties in Missouri except Jackson, Lafayette, Saline, Cooper, Moniteau, Cole, Osage, Gasconade, Franklin, St. Louis, and all Counties in the State of Missouri lying south thereof.

(Secs. 4–7, 23 Stat. 32, as amended, secs. 1, 2, 32 Stat. 791–792, as amended, secs. 1–4, 33 Stat. 1264, as amended, 1265, as amended; 21 U.S.C. 111–113, 115, 117, 120, 121, 123–126; 19 F.R. 74, as amended)

Effective date. The foregoing amendments shall become effective upon issuance.

The amendments add the entire States of Minnesota, New Jersey, and Pennsylvania, and Allegan, Arenac, Barry, Bay, Berrien, Branch, Calhoun, Cass, Clare, Clinton, Eaton, Genesee, Gladwin, Gratiot Hillsdale, Huron, Ingham, Ionia, Iosco, Isabella, Jackson, Kalamazoo, Kent, Lake, Lapeer, Lenawee, Livingston, Macomb, Mason, Mecosta, Midland, Monroe, Montcalm, Muskegon, Newaygo, Oakland, Oceana, Ogemaw, Osceola, Ottawa, Saginaw, Sanilac, Shiawassee, St. Clair, St. Joseph, Tuscola, Van Buren, Washtenaw, and Wayne Counties in the State of Michigan, to the list of free areas and delete such States and specified counties from the list of infected and eradication areas as sheep scabies is no longer known to exist therein. The entire State of Michigan has now been designated as a free area. Hereafter, the restrictions pertaining to the interstate movement of sheep from or into infected and eradication areas as contained in 9 CFR Part 74, as amended, will not apply to Minnesota, Michigan, New Jersey, or Pennsylvania. However, the restrictions in said Part 74 pertaining to the interstate movement of sheep from or into free areas will apply to these four States.

The amendments relieve certain restrictions presently imposed and must be made effective immediately to be of maximum benefit to persons subject to the restrictions which are relieved. Accordingly, under section 4 of the Administrative Procedure Act (5 U.S.C. 1003), it is found upon good cause that notice and other public procedure with respect to the amendments are impracticable and contrary to the public interest, and the amendments may be made effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 14th day of June 1963.

M. R. CLARKSON,
Acting Administrator,
Agricultural Research Service.

[F.R. Doc. 63-6508; Filed, June 19, 1963; 8:56 a.m.]

Title 10—ATOMIC ENERGY

Chapter I—Atomic Energy Commission

PART 1—STATEMENT OF ORGANIZATION, DELEGATIONS AND GENERAL INFORMATION

Miscellaneous Amendments

Notice is hereby given of the amendment of the Statement of Organization, Delegations and General Information of the United States Atomic Energy Commission, 10 CFR Part 1, published in the FEDERAL REGISTER on December 29, 1961 (26 F.R. 12729–12745), as amended.

The present amendments describe the delegations of authority to consider, ascertain, adjust, determine and settle, subject to the limitations set forth in the Federal Tort Claims Act, claims not in excess of $2,500 against the United States which are based on negligent acts or omissions of employees of the Atomic Energy Commission.

Pursuant to the Administrative Procedure Act, 1 CFR 13.2, and the Atomic Energy Act of 1954, as amended, the following amendments of Part 1 of the Commission's regulations are published as a document subject to codification, effective upon publication in the FEDERAL REGISTER.

1. Section 1.5 *Delegation and redelegation of authority* is amended by the addition of a new paragraph (c)(3) to read as follows:

(3) Subject to the limitations of the Federal Tort Claims Act, to consider, ascertain, adjust, determine and settle any claim against the United States for money only where the total amount of the claim does not exceed $2,500 on account of damage to or loss of property or on account of personal injury or death, by the negligent or wrongful act or omission of any employee of the Atomic Energy Commission, while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant for such damage, loss, injury or death, in accordance with the law of the place where the act or omission occurred.

2. Section 1.20 *Office of the General Manager* is amended by the addition of a new paragraph (h) to read as follows:

(h) The Deputy General Manager and the Assistant General Manager are authorized and directed, subject to the limitations of the Federal Tort Claims Act, to consider, ascertain, adjust, determine and settle any claim against the United States for money only where the total amount of the claim does not exceed $2,500 on account of damage to or loss of property or on account of personal injury or death, by the negligent or wrongful act or omission of any employee of the Atomic Energy Commission, while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant for such damage, loss, injury, or death, in accordance with the law of the place where the act or omission occurred.

3. Section 1.200 *Chicago Operations Office* is amended by the addition of a new paragraph (f) to read as follows:

(f) The Manager and Deputy Manager, Chicago Operations Office, are authorized and directed to exercise the settlement authority as described in § 1.5(c)(3).

4. Section 1.201 *Idaho Operations Office* is amended by the addition of a new paragraph (e) to read as follows:

(e) The Manager and Deputy Manager, Idaho Operations Office, are au-

thorized and directed to exercise the settlement authority as described in § 1.5 (c) (3).

5. Section 1.202 *Oak Ridge Operations Office* is amended by the addition of a new paragraph (f) to read as follows:

(f) The Manager, Deputy Manager, and the Assistant Manager for Administration, Oak Ridge Operations Office, are authorized and directed to exercise the settlement authority as described in § 1.5(c) (3).

6. Section 1.203 *New York Operations Office* is amended by the addition of a new paragraph (e) to read as follows:

(e) The Manager and Deputy Manager, New York Operations Office, are authorized and directed to exercise the settlement authority as described in § 1.5(c) (3).

7. Section 1.204 *Hanford Operations Office* is amended by the addition of a new paragraph (e) to read as follows:

(e) The Manager and the Assistant Manager for Administration, Hanford Operations Office, are authorized and directed to exercise the settlement authority as described in § 1.5(c) (3).

8. Section 1.205 *Savannah River Operations Office* is amended by the addition of a new paragraph (e) to read as follows:

(e) The Manager and Deputy Manager, Savannah River Operations Office, are authorized and directed to exercise the settlement authority as described in § 1.5(c) (3).

9. Section 1.206 *Albuquerque Operations Office* is amended by the addition of a new paragraph (g) to read as follows:

(g) The Manager and Deputy Manager, Albuquerque Operations Office, are authorized and directed to exercise the settlement authority as described in § 1.5(c) (3).

10. Section 1.207 *San Francisco Operations Office* is amended by the addition of a new paragraph (e) to read as follows:

(e) The Manager and Deputy Manager, San Francisco Operations Office, are authorized and directed to exercise the settlement authority as described in § 1.5(c) (3).

11. Section 1.208 *Nevada Operations Office* is amended by the addition of a new paragraph (d) to read as follows:

(d) The Manager, Deputy Manager, and the Assistant Manager for Administration, Nevada Operations Office, are authorized and directed to exercise the settlement authority as described in § 1.5(c) (3).

12. Section 1.210 *Grand Junction Office* is amended by the addition of a new paragraph (d) to read as follows:

(d) The Manager and the Assistant Manager for Administration, Grand Junction Office, are authorized and directed to exercise the settlement authority as described in § 1.5(c) (3).

13. Section 1.215 *Brookhaven Office* is amended by the addition of a new paragraph (d) to read as follows:

(d) The Manager, Brookhaven Office, is authorized and directed to exercise the settlement authority as described in § 1.5(c) (3).

14. Section 1.225 *Pittsburgh Naval Reactor Office* is amended by the addition of a new paragraph (d) to read as follows:

(d) The Manager, Pittsburgh Naval Reactors Office, is authorized and directed to exercise the settlement authority as described in § 1.5(c) (3).

15. Section 1.226 *Schenectady Naval Reactors Office* is amended by the addition of a new paragraph (d) to read as follows:

(d) The Manager, Schenectady Naval Reactors Office, is authorized and directed to exercise the settlement authority as described in § 1.5(c) (3).

(Sec. 161, 68 Stat. 948; 42 U.S.C. 2201)

Dated at Washington, D.C., this 6th day of June 1963.

For the Atomic Energy Commission.

WOODFORD B. MCCOOL,
Secretary.

[F.R. Doc. 63-6462; Filed, June 19, 1963; 8:45 a.m.]

Title 15—COMMERCE AND FOREIGN TRADE

Subtitle A—Office of the Secretary of Commerce

PART 7—RULES APPLICABLE TO THE AIRCRAFT LOAN GUARANTEE PROGRAM

Explanatory statement. Public Law 87-820; 76 Stat. 936, of October 15, 1962 extended for an additional five-year period the Aircraft Loan Guarantee Act of September 7, 1957 and transferred responsibility for its administration to the Secretary of Commerce. In addition it raised from $5,000,000 to $10,000,000 the limit on the amount of any loan or loans to any carrier.

The Secretary of Commerce has delegated to the Under Secretary of Commerce for Transportation the powers and duties vested in him by Public Law 87-820.

On January 6, 1962, the Civil Aeronautics Board prescribed procedural regulations for the Aircraft Loan Guarantee Program. These regulations have remained in effect under the terms of Public Law 87-820, until terminated, set aside, or repealed by the Secretary.

The rules adopted by the Civil Aeronautics Board on January 6, 1962, have been determined by the Under Secretary of Commerce for Transportation to be substantially adequate with minor amendments.

Since the amendments are not of a substantive nature, but of agency procedure, notice and public participation are not required and the amended regulations may become effective upon less than 30 days' notice.

In consideration of the above, the Under Secretary of Commerce for Transportation hereby issues Rules applicable to the Aircraft Loan Guarantee Program, 15 CFR, Subtitle A, Part 7, which supersede the Civil Aeronautics Board Procedural Regulation for Loan Guarantees, 14 CFR Part 302, Subpart H dated January 6, 1962.

Sec.
7.1 Applicability of this part.
7.2 Institution of proceeding.
7.3 Contents of applications.
7.4 Action taken on applications.
7.5 Deviations from the terms of agreements.

AUTHORITY: §§ 7.1 to 7.5 issued under 76 Stat. 936, 49 U.S.C. and Department Order 128 dated May 9, 1963; 28 F.R. 5096.

§ 7.1 Applicability of this part.

This part sets forth the special rules applicable to the filing and processing of applications for aircraft loan guarantees as provided in the Act of September 7, 1962, 71 Stat. 629 and as amended by Act of October 15, 1962, 76 Stat. 936.

§ 7.2 Institution of proceeding.

A proceeding to obtain the Under Secretary of Commerce for Transportation's approval for government guarantee of an aircraft purchase loan may be instituted by the filing of an original and 7 copies of Form SEC-378 and Form SEC-379 by the lender and air carrier respectively, together with an original and 4 copies of supporting documents. Form SEC-378 and 379 may be obtained from the Under Secretary of Commerce for Transportation, Washington 25, D.C.

§ 7.3 Contents of applications.

(a) Form SEC-378—*Application for Aircraft Loan Guarantee.* This form contains requests for the following information: (1) Name and address of lender, (2) name and address of carrier, (3) amount of loan, maturity date, interest rate, purchase price, term of loan (years), guarantee requested, (4) disbursement schedule, (5) repayment schedule, (6) collateral, (7) yes and no answer as to whether lender would grant this loan, or a comparable loan, without government guarantee, and (8) the lender's name, an authorized signature, title, and date.

(b) Form SEC-379—*Statement of Carrier in Support of Application for Aircraft Loan Guarantee.* This form contains requests for the following information: (1) A list of all banks (or other sources) from whom the air carrier has attempted to negotiate a loan during the past year, (2) a yes or no answer as to whether the air carrier has attempted to obtain equity capital during the past year, (3) the type, quantity, and cost of equipment to be purchased with the proceeds of this loan, (4) name and address of seller(s) of aircraft and major groups of spare parts, (5) the purchase plan, (6) use to be made of new equipment, (7) expected financial effect of new equipment, (8) common stockholders controlling, directly or indirectly, more than 5 percent of the stock of both

the lender and the air carrier, and (9) the air carrier's name and authorized signature, title, and date.

§ 7.4 Action taken on applications.

Upon receipt of the application and supplemental material, the Under Secretary of Commerce for Transportation may communicate with the Civil Aeronautics Board, the lenders and air carriers where necessary, in order to avail himself of additional or clarifying information before approving or disapproving the application.

§ 7.5 Deviations from the terms of agreements.

Following the grant of a loan guarantee, no deviations from the terms of the guarantee and loan agreements may be made without prior approval from the Under Secretary of Commerce for Transportation. An original and four copies of requests for such approval and three copies of any supporting documents must be filed with the Under Secretary of Commerce for Transportation. Information contained in such requests and supporting documents shall be withheld from public disclosure during the life of the loan guarantee involved unless the Under Secretary of Commerce for Transportation finds that disclosure of such information is required in the public interest.

NOTE: The reporting requirements contained herein have been approved by the Bureau of the Budget in accordance with the Federal Reports Act of 1942.

Dated: June 7, 1963.

CLARENCE D. MARTIN, Jr.,
Under Secretary of Commerce for Transportation.

[F.R. Doc. 63-6505; Filed, June 19, 1963; 8:56 a.m.]

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER A—GENERAL

PART 8—COLOR ADDITIVES

Subpart D—Listing of Color Additives for Food Use Exempt From Certification

ANNATTO EXTRACT; LISTING FOR FOOD USE; EXEMPTION FROM CERTIFICATION

Pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 706 (b)(1), (c)(2), 74 Stat. 399, 402; 21 U.S.C. 376 (b)(1), (c)(2)), and under the authority delegated to him by the Secretary of Health, Education, and Welfare (25 F.R. 8625), the Commissioner of Food and Drugs, based on a petition filed by the Annatto Color Testing Committee, 14 Proudfit Street, Madison, Wisconsin, and other relevant material, finds that annatto extract, when used in accordance with the conditions prescribed in this order, is safe for use in or on foods and that certification is not necessary for the protection of the public health. *Therefore, it is ordered,* That Part 8 be amended by adding to Subpart D the following new section:

§ 8.305 Annatto extract.

(a) *Identity.* (1) The color additive annatto extract is an extract prepared from annatto seed, Bixa orellana L., using any one or an appropriate combination of the food-grade extractants listed in subdivision (i) and (ii) of this subparagraph:

(i) Alkaline aqueous solution, alkaline propylene glycol, ethyl alcohol or alkaline solutions thereof, edible vegetable oils or fats, mono- and diglycerides from the glycerolysis of edible vegetable oils or fats.

The alkaline alcohol or aqueous extracts may be treated with food-grade acids to precipitate annatto pigments, which are separated from the liquid and dried, with or without intermediate recrystallization, using the solvents listed under subdivision (ii) of this subparagraph. Food-grade alkalis or carbonates may be added to adjust alkalinity.

(ii) Acetone, ethylene dichloride, hexane, isopropyl alcohol, methyl alcohol, methylene chloride, trichloroethylene.

(2) Color additive mixtures made with annatto extracts may contain as diluents only those substances that, if used in foods, are not food additives within the meaning of section 201(s) of the act, or, if they are food additives, are authorized for a specific use or uses under the provisions of Part 121 of this chapter.

(b) *Specifications.* Annatto extract, including pigments precipitated therefrom, conforms to the following specifications:

(1) Arsenic (As)—Not more than 3 parts per million.

Lead (Pb)—Not more than 10 parts per million.

(2) When solvents listed under paragraph (a)(1)(ii) are used, it shall contain no more solvent residue than is permitted of the corresponding solvents in spice oleoresins under applicable food additive regulations in Part 121 of this chapter.

(c) *Uses and restrictions.* Annatto extract may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act and the use of added color is not authorized by such standards.

(d) *Labeling.* In addition to all other information required by the act, labels of annatto extract and color additive mixtures prepared therefrom shall bear information showing that the color is derived from annatto seed, and shall declare all ingredients, with the exception of residues of solvents listed in paragraph (a)(1)(ii), by their specific common or usual names.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

Any person who will be adversely affected by the foregoing order may at any time within 30 days from the date of its publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington 25, D.C., written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing, and such objections must be supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof. All documents shall be filed preferably in quintuplicate.

Effective date. This order shall become effective 60 days from the date of its publication in the FEDERAL REGISTER, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be announced by publication in the FEDERAL REGISTER.

(Sec. 706, 74 Stat. 399, 402; 21 U.S.C. 376)

Dated: June 13, 1963.

GEO. P. LARRICK,
Commissioner of Food and Drugs.

[F.R. Doc. 63-6488; Filed, June 19, 1963; 8:51 a.m.]

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 121—FOOD ADDITIVES

Subpart D—Food Additives Permitted in Food for Human Consumption

SORBITAN MONOSTERATE; POLYSORBATE 60

The Commissioner of Food and Drugs, having evaluated the data submitted in a petition filed by Atlas Chemical Industries, Inc., Wilmington 99, Delaware, and other relevant material, has concluded that the food additive regulations should be amended to prescribe additional safe uses of the above-identified substances in certain foods. Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786; 21 U.S.C. 348(c)(1)), and under the authority delegated to the Commissioner by the Secretary of Health, Education, and Welfare (25 F.R. 8625), §§ 121.1029 and 121.1030 are amended as follows:

1. Section 121.1029(c) is amended by adding thereto a new subparagraph (4), which reads:

§ 121.1029 Sorbitan monostearate.

* * * * *

(c) * * *

(4) As an emulsifier in cake icing or cake filling containing shortening, alone or in combination with polysorbate 60 (polyoxyethylene (20) sorbitan monostearate), as follows:

(i) It is used alone in an amount not to exceed 7,000 parts per million (0.7 per-

cent) of the weight of the finished cake icing or cake filling.

(ii) It is used with polysorbate 60 (polyoxyethylene (20) sorbitan monostearate) in any combination providing no more than 7,000 parts per million (0.7 percent) of sorbitan monostearate and no more than 4,600 parts per million (0.46 percent) of polysorbate 60 (polyoxyethylene (20) sorbitan monostearate), provided that the total combination does not exceed 10,000 parts per million (1.0 percent) of the weight of the finished cake icing or cake filling.

2. Section 121.1030(c) is amended by adding thereto a new subparagraph (5), which reads:

§ 121.1030 Polysorbate 60 (polyoxyethylene (20) sorbitan monostearate).

* * * * * * *

(c) * * *

(5) As an emulsifier in cake icing or cake filling containing shortening, alone or in combination with sorbitan monostearate, as follows:

(i) It is used alone in an amount not to exceed 4,600 parts per million (0.46 percent) of the weight of the finished cake icing or cake filling.

(ii) It is used with sorbitan monostearate in any combination providing no more than 4,600 parts per million (0.46 percent) of polysorbate 60 (polyoxyethylene (20) sorbitan monostearate) and no more than 7,000 parts per million (0.70 percent) of sorbitan monostearate, provided that the total combination does not exceed 10,000 parts per million (1.0 percent) of the finished cake icing or cake filling.

Any person who will be adversely affected by the foregoing order may at any time within 30 days from the date of its publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington 25, D.C., written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof. All documents shall be filed in quintuplicate.

Effective date. This order shall be effective on the date of its publication in the FEDERAL REGISTER.

(Sec. 409(c)(1), 72 Stat. 1786; 21 U.S.C. 348 (c)(1))

Dated: June 13, 1963.

GEO. P. LARRICK,
Commissioner of Food and Drugs.

[F.R. Doc. 63-6489; Filed, June 19, 1963; 8:52 a.m.]

SUBCHAPTER C—DRUGS

PART 146c—CERTIFICATION OF CHLORTETRACYCLINE (OR TETRACYCLINE) AND CHLORTETRACYCLINE- (OR TETRACYCLINE-) CONTAINING DRUGS

Demethylchlortetracycline Syrup (Demethylchlortetracycline Oral Drops)

Under the authority vested in the Secretary of Health, Education, and Welfare by the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463, as amended; 21 U.S.C. 357) and delegated to the Commissioner of Food and Drugs by the Secretary (25 F.R. 8625), the regulations for the certification of chlortetracycline and chlortetracycline containing drugs are amended by changing the third sentence of paragraph (a) of § 146c.255 *Demethylchlortetracycline syrup (demethylchlortetracycline oral drops)* to read as follows: "The pH is not less than 4.0 and not more than 5.8."

Notice and public procedure and delayed effective date are not necessary prerequisites to the promulgation of this order, and I so find, since the change does not affect the stability or effectiveness of the drug involved.

Effective date. This order shall become effective on the date of its publication in the FEDERAL REGISTER.

(Sec. 507, 59 Stat. 462, as amended; 21 U.S.C. 357)

Dated: June 13, 1963.

GEO. P. LARRICK,
Commissioner of Food and Drugs.

[F.R. Doc. 63-6490; Filed, June 19, 1963; 8:52 a.m.]

Title 32—NATIONAL DEFENSE

Chapter I—Office of the Secretary of Defense

SUBCHAPTER E—DEFENSE CONTRACT FINANCING

PART 163—DEFENSE CONTRACT FINANCING REGULATIONS

Miscellaneous Amendments

The following amendments to this part are issued by direction of the Assistant Secretary of Defense (Installations and Logistics) pursuant to the authority contained in Department of Defense Directive No. 4105.30, dated March 11, 1959 (24 F.R. 2260), as amended, and 10 U.S.C. 2202.

1. Sections 163.13, 163.14 and 163.15 are revised and § 163.15-1 is added, as follows:

§ 163.13 Scope of subpart.

This subpart sets forth basic policies applicable to guaranteed loans, advance payments, and progress payments. Policies and procedures more particularly pertaining to the specific methods of contract financing are contained in the subparts of this part relating to each method of financing. Sections 163.14 and 163.15 also deal with other payments to contractors.

§ 163.14 Acceleration of payments.

Payments must be made promptly on all contracts when due. It is of continuing importance that there be acceleration of all proper payments earned by contractors, including progress payments. Undue delays by the Government in determining amounts due to contractors or in making timely payment of amounts earned by contractors would impose financing burdens on contractors and may amount to extensions of credit by contractors to the Government.

§ 163.15 Timely action.

In connection with requests for provision of progress payments, advance payments, or loan guarantees, there must be timely action, no unwarranted delay, and no hestitation to make proper contract financing provisions. Likewise, with regard to other payments to contractors, not constituting contract financing, amounts properly payable to contractors must be ascertained promptly and paid expeditiously. Responsible personnel shall utilize vigorously all proper means available to them for ascertainment and payment of amounts payable to contractors as rapidly as possible. Whenever it appears that it will be necessary to provide additional funds on contracts, it is of great importance that there be appropriate early action to assure the availability of funds for payment of amounts earned by contractors. Significant examples of situations in which it is of particular importance that there be timely and effective action, and no unnecessary Government delay, include:

(a) Negotiation and agreement on amounts earned by contractors (1) pursuant to change orders (see § 1.201-1 of this chapter) or unilateral contract modifications (see § 1.201-2 of this chapter), (2) for other equitable adjustments pursuant to contracts, (3) under contract provisions for price revision or fee adjustment, (4) under contract provisions for payment for special tooling, and (5) for final payments on contract terminations.

(b) Retroactive establishment of overhead billing rates under contracts providing for provisional overhead billing rates;

(c) Contract provision to support billing and payment for (1) cost overruns properly incurred by contractors after appropriate notice in conformity to contract provisions, and (2) spare parts deliveries effected before issuance of appropriate contract supplement; and

(d) Definitization of letter contracts.

§ 163.15-1 Supplemental agreement.

After negotiations involving agreement on an amount to be paid to a contractor, appropriate supplemental agreement shall be prepared expeditiously and executed without delay. To the very greatest extent practicable, all such sup-

plemental agreements and also those supplemental agreements involving refunds by contractors (§ 163.105 of this part) shall be limited to appropriate coverage of the matters directly related and leading to the contemplated payment by or to the Government; and their preparation and issuance shall not be held up pending the consummation of agreements on other separate matters on which contract amendments are desired or contemplated.

§ 163.101 Prompt ascertainment and collection; controls; records.

2. A new sentence is added to § 163.101, as follows: "On the need for prompt ascertainment and payment of amounts payable to contractors, see §§ 163.14 and 163.15 of this part."

3. Sections 163.104–2 and 163.106 are revised to read as follows:

§ 163.104–2 Amount fixed unilaterally.

The amount of indebtedness fixed unilaterally shall be such as is proper under the circumstances, and must not exceed the amount which would have been considered acceptable for a negotiated agreement fixing the amount of the indebtedness. The amount so determined shall be based on the merits of (§ 163.103), and consistent with the contract (§ 163.104–1). At or before the time of making the demand (§ 163.106), by a contracting officer, the contracting officer shall make appropriate decision under the Disputes clause of the contract and shall give notice of the opportunity to appeal as provided by § 1.314 of this chapter.

§ 163.106 Demand.

(a) The office which first determines an amount to be due shall make immediate demand for payment. This demand should (1) appropriately explain the indebtedness, (2) inform the contractor that any amount not paid within 30 days from the date of the demand will bear interest at the rate of 6 percent per annum from the date of the demand (or any earlier date established pursuant to the contract), to be adjusted only when and as provided by this subpart, and (3) notify the contractor that it may submit a proposal for postponement of payments if immediate payment is not practicable or if the amount is disputed.

(b) For decision pursuant to the Disputes clause and notice of opportunity to appeal, see § 163.104–2. When § 163.118 (iii) is operative to fix the date when a debt is due, the transmittal mentioned in § 163.118(iii) shall include or be accompanied by the demand required by this section.

4. New § 163.116–2 is added; §§ 163.118 and 163.119 are revised; and new §§ 163.119–1 and 163.122 are added, as follows:

§ 163.116–2 Non-existent debt.

Interest is a charge or compensation for the use or retention of money. Hence, whenever the principal amount of a particular asserted indebtedness is reduced, as finally determined in a particular case, interest is chargeable only on the principal amount of the debt as finally determined. To the extent that principal debt is eliminated, interest of course is also eliminated.

§ 163.118 Contract clause—interest.

Except as provided in § 163.119, all contracts for procurement, or for sale or use of Government property or services, shall include the following clause:

INTEREST (MAY 1963)

Notwithstanding any other provision of this contract, unless paid within 30 days all amounts that become payable by the Contractor to the Government under this contract (net of any applicable tax credit under the Internal Revenue Code) shall bear interest at the rate of six percent per annum from the date due until paid and shall be subject to adjustments as provided by Part 6 of Appendix E of the Armed Services Procurement Regulation, as in effect on the date of this contract. Amounts shall be due upon the earliest one of (i) the date fixed pursuant to this contract, (ii) the date of the first written demand for payment, consistent with this contract, (iii) the date of transmittal by the Government to the Contractor of a proposed supplemental agreement to confirm completed negotiations fixing the amount, or (iv) if this contract provides for revision of prices, the date of written notice to the Contractor stating the amount of refund payable in connection with a pricing proposal or in connection with a negotiated pricing agreement not confirmed by contract supplement.

§ 163.119 Exceptions to interest clause requirement.

Contract provision for interest need not be included in (a) small purchases (see Subpart F, Part 3 of this chapter); (b) purchases described in §§ 16.303, 16.304, 16.501 and 16.504 of this chapter, or in Part 5 of this chapter; (c) purchases under indefinite delivery type contracts existing before the effective date of this subpart; (d) amendments of contracts existing before the effective date of this subpart; or (e) contracts with agencies of the United States Government, foreign governments or agencies thereof, State or local governments or agencies thereof, or nonprofit contracts with nonprofit educational or research institutions. Further exceptions may be established by the Contract Finance Committee (§ 163.12–3 of this part), with the approval of the Assistant Secretary of Defense (Comptroller) or his representative.

§ 163.119–1 Further exceptions.

The following further exceptions have been established pursuant to the second sentence of § 163.119:

(a) Contracts for instructions of military personnel, or ROTC personnel, at civilian schools, colleges, and universities; and

(b) Basic agreements with telephone companies, under which communications services and facilities will be ordered, and purchases under such agreements.

§ 163.122 Delays or failures of notice or demand.

It is expected that demands (§§ 163.106, 163.106–2, 163.107, and 163.118(ii)) and notices (§ 163.118(iv)) will bear a date closely approximating the date of transmittal; such demands and notices, and the supplemental agreements mentioned in § 163.118(iii), will be delivered in due course to the contractors. It could happen occasionally that there is undue delay after the stated date of a demand or notice, before its dispatch, or that there is undue delay in the mails or other selected means of communication after transmittal of a demand, notice, or supplemental agreement or that a demand, notice, or supplemental agreement is not in fact received by the contractor, and that the nonreceipt is not the result of any act or omission on the part of the contractor. In such cases, the due date of the debt and the starting time for accrual of interest thereon will be extended to such time as is fair and reasonable under the particular circumstances. For example, if there is substantial delay between the date of a demand or notice, and the actual date of its dispatch or transmittal, the actual date of dispatch or transmittal would apply instead of the date stated on the demand or notice. Such delay should not be allowed to happen. Also, for example, if there is unusual delay in the mails or other selected form of communication, after dispatch or transmittal of a demand, notice, or supplemental agreement, the date of receipt by the contractor would apply instead of the earlier date otherwise applicable, and if the demand, notice, or supplemental agreement, as the case may be, is not received by the contractor, the date of transmittal of a second demand, notice, or supplemental agreement would apply instead of the earlier date otherwise applicable.

[ASPR Rev. 1, May 23, 1963] (Sec. 2202, 70A Stat. 120; 10 U.S.C. 2202)

J. C. LAMBERT,
Major General, U.S. Army,
The Adjutant General.

[F.R. Doc. 63–6464; Filed, June 19, 1963; 8:46 a.m.]

Title 32A—NATIONAL DEFENSE, APPENDIX

Chapter X—Oil Import Administration, Department of the Interior

[O.I. Reg. 1; (Rev. 3) Amdt. 3]

OI REG. I—OIL IMPORT REGULATION

Allocations of Crude Oil

1. Section 10 of Oil Import Regulation 1 (Revision 3) (27 F.R. 12444) is amended to read as follows:

Sec. 10. Allocations of crude oil and unfinished oils—Districts I–IV.

(a) The quantity of imports of crude oil and unfinished oils determined to be available for allocation in Districts I–IV for the allocation period July 1, 1963 through December 31, 1963 shall be allocated by the Administrator among eligible applicants as provided in paragraphs (b) and (c) of this section.

(b) Except as provided in paragraph (c) of this section, each eligible applicant shall receive an allocation based on refinery inputs for the year ending

March 31, 1963 and computed according to the following schedule:

Average B/D input	*Percent of input*
0–10,000	12.5
10–30,000	11.5
30–100,000	9.2
100,000 plus	5.4

(c) (1) Except as provided in subparagraph (2) of this paragraph, if an eligible applicant imported crude oil pursuant to an allocation under the Voluntary Oil Import Program and if an allocation computed under paragraph (b) of this section would be less than 65.0 percent of the applicant's last allocation of imports of crude oil under the Voluntary Oil Import Program, the applicant shall, nevertheless, receive an allocation under this section equal to 65.0 percent of his last allocation of imports of crude oil under the Voluntary Oil Import Program.

(2) If an applicant imported crude oil pursuant to an allocation under the Voluntary Oil Import Program which reflected imports of crude oil that would now be exempt from restrictions pursuant to clause (4) of paragraph (a) of section 1 of Proclamation 3279, as amended, and if an allocation computed under paragraph (b) of this section would be less than 58.75 percent of the applicant's last allocation of imports of crude oil under the Voluntary Oil Import Program, the applicant shall, nevertheless, receive an allocation under this section equal to 58.75 percent of his last allocation of imports of crude oil under the Voluntary Oil Import Program.

(d) No allocation made pursuant to this section shall entitle a person to a license which will allow the importation of unfinished oils in excess of 10 percent of the allocation.

(e) No allocation made pursuant to this section may be sold, assigned, or otherwise transferred.

2. Section 11 of Oil Import Regulation 1 (Revision 3) (27 F.R. 12444) is amended to read as follows:

Sec. 11. Allocations of crude oil and unfinished oils—District V.

(a) The quantity of imports of crude oil and unfinished oils determined to be available for allocation in District V for the allocation period July 1, 1963 through December 31, 1963 shall be allocated by the Administrator among eligible applicants as provided in paragraphs (b) and (c) of this section.

(b) Except as provided in paragraph (c) of this section, each eligible applicant shall receive an allocation based on refinery inputs for the year ending March 31, 1963, and computed according to the following schedule:

Average B/D input	*Percent of input*
0–10,000	50.0
10–30,000	25.9
30,000 plus	8.57

(c) (1) Except as provided in subparagraph (2) of this paragraph, if an eligible applicant imported crude oil pursuant to an allocation under the Voluntary Oil Import Program and if an allocation computed under paragraph (b) of this section would be less than 57.0 percent of the applicant's last allocation of imports of crude oil under the Voluntary Oil Import Program, the applicant shall, nevertheless, receive an allocation under this section equal to 57.0 percent of his last allocation of imports of crude oil under the Voluntary Oil Import Program.

(2) If an applicant imported crude oil pursuant to an allocation under the Voluntary Oil Import Program which reflected imports of crude oil that would now be exempt from restrictions pursuant to clause (4) of paragraph (a) of section 1 of Proclamation 3279, as amended, and if an allocation computed under paragraph (b) of this section would be less than 52.0 percent of the applicant's last allocation of imports of crude oil under the Voluntary Oil Import Program, the applicant shall, nevertheless, receive an allocation under this section equal to 52.0 percent of his last allocation of imports of crude oil under the Voluntary Oil Import Program.

(d) (1) Allocations made pursuant to this section shall not permit the importation of unfinished oils in excess of 10 percent of the permissible imports of crude oil. With respect to any allocation made pursuant to this section, the Administrator upon request shall issue a license permitting the importation of unfinished oils in an amount not in excess of 10 percent of the allocation. If the total quantity of unfinished oils applied for is less than 10 percent of the permissible imports of crude oil, the Administrator may to that extent increase the percentage amount of unfinished oils specified in licenses of persons who request such increases.

(2) Each person making such a request shall receive an increase in the proportion that his allocation bears to the total of allocations made to all persons requesting increases. Each barrel of unfinished oil imported shall be deemed to be the equivalent of one barrel of crude oil and will be so charged against the person's license by the respective Collectors of Customs.

(3) The permissible percentage of imports of unfinished oils and the equivalence of unfinished oils to crude oil may be changed during the allocation period, if necessary to prevent impairing accomplishment of the purposes of the program. Such a change will be made only after notice of proposed rule making and will not become effective until the 30th calendar day following publication in the FEDERAL REGISTER of the amendment making such change.

(e) No allocation made pursuant to this section may be sold, assigned, or otherwise transferred.

Because allocations must be made and licenses issued for the allocation period beginning July 1, 1963, it is impracticable to give notice of proposed rule making on, or to delay the effective date of, this amendment. Accordingly, this amendment shall become effective immediately.

STEWART L. UDALL,
Secretary of the Interior.

JUNE 18, 1963.

[F.R. Doc. 63-6549; Filed, June 19, 1963; 8:57 a.m.]

Title 43—PUBLIC LANDS: INTERIOR

Chapter I—Bureau of Land Management, Department of the Interior

APPENDIX—PUBLIC LAND ORDERS

[Public Land Order 3102]

[Los Angeles 0156636]

CALIFORNIA

Partly Revoking the Executive Order of January 24, 1914; Public Water Reserve No. 14

By virtue of the authority vested in the President by section 1 of the Act of June 25, 1910 (36 Stat. 847; 43 U.S.C. 141), and pursuant to Executive Order No. 10355 of May 26, 1952, it is ordered as follows:

1. The Executive Order of January 24, 1914, creating Public Water Reserve No. 14, California No. 2, so far as it affects the following described lands, is hereby revoked:

SAN BERNARDINO MERIDIAN

T. 15 S., R. 7 E.,
Sec. 13, W½SW¼ and SE¼SW¼;
Sec. 14, E½SE¼.

The areas described aggregate approximately 200 acres.

2. Until 10:00 a.m., on December 13, 1963, the State of California shall have a preferred right of application to select the lands as provided by subsection (c) of section 2 of the Act of August 27, 1958 (72 Stat. 928; 43 U.S.C. 851, 852). On and after that date and hour the lands shall become subject to application, petition, and selection, generally, subject to valid existing rights, the provisions of existing withdrawals, and the requirements of applicable law. All valid applications except preference right applications from the State, received prior to 10:00 a.m. on December 13, 1963, shall be considered as simultaneously filed at that time.

3. The lands have been open to applications and offers under the mineral leasing laws, and to location for metalliferous minerals. They will be open to location for nonmetalliferous minerals under the United States mining laws beginning at 10:00 a.m. on December 13, 1963.

Inquiries concerning the lands should be addressed to the Manager, Land Office, Bureau of Land Management, Riverside, California.

JOHN A. CARVER, Jr.,
Assistant Secretary of the Interior.

JUNE 14, 1963.

[F.R. Doc. 63-6472; Filed June 19, 1963; 8:48 a.m.]

[Public Land Order 3103]

[Oregon 010029]

OREGON

Opening of Lands Formerly in Water Power Project No. 57

1. In an order issued March 19, 1963, the Federal Power Commission vacated

the withdrawal created pursuant to the filing of an application for preliminary permit for proposed Project No. 57, for the following-described lands:

WILLAMETTE MERIDIAN

T. 10 S., R. 13 E.,
Sec. 29, N½SW¼;
Sec. 30, NE¼SE¼;
Sec. 32, E½NE¼;
Sec. 33, SE¼SW¼, NW¼SW¼ and SW¼NW¼.
T. 11 S., R. 13 E.,
Sec. 3, lots 3, 4 and S½NW¼;
Sec. 4, lots 1 and 2.

The areas described aggregate approximately 542 acres, of which lot 3, sec. 3, T. 11 S., R. 13 E. is patented.

2. At 10:00 a.m. on July 20, 1963, the lands shall become subject to application, petition and selection generally, subject to valid existing rights, the provisions of existing withdrawals, and the requirements of applicable law. All valid applications received prior to 10:00 a.m. on July 20, 1963, will be considered as simultaneously filed at that time.

3. The lands have been open to applications and offers under the mineral leasing laws, and to location under the United States mining laws, subject to the provisions of the Act of August 11, 1955 (69 Stat. 682; 30 U.S.C. 621).

4. The State of Oregon has waived its preference rights of application under subsection (c) of Section 2 of the Act of August 27, 1958 (72 Stat. 928; 43 U.S.C. 851, 852), and under Section 24 of the Federal Power Act of 1920, as amended.

Inquiries concerning the lands should be addressed to the Manager, Land Office, Bureau of Land Management, Portland, Oregon.

JOHN A. CARVER, Jr.,
Assistant Secretary of the Interior.

JUNE 14, 1963.

[F.R. Doc. 63-6473; Filed, June 19, 1963; 8:48 a.m.]

[Public Land Order 3104]

[Oregon 013263]

OREGON

Revoking Stock Driveway Withdrawal No. 263, Oregon No. 40

By virtue of the authority contained in section 10 of the Act of December 29, 1916 (39 Stat. 865; 43 U.S.C. 300), as amended, it is ordered as follows:

1. The departmental order of January 22, 1941, which withdrew the following-described lands for stock driveway purposes as Stock Driveway Withdrawal No. 263, Oregon No. 40, is hereby revoked:

WILLAMETTE MERIDIAN

T. 2 N., R. 47 E.,
Sec. 4, E½SE¼;
Sec. 9, E½NE¼.

Containing approximately 160 acres.

2. The lands are located about 30 miles northeast of Enterprise, in Wallowa County, Oregon.

3. Beginning at 10:00 a.m. on July 20, 1963, the lands shall be subject to application and selection generally, subject to valid existing rights, and the requirements of applicable law. All valid applications and selections under the nonmineral public land laws received prior to 10:00 a.m. on July 20, 1963, shall be considered as simultaneously filed at that time.

4. The lands have been open to application and offers under the mineral leasing laws, and to location under the United States mining laws pursuant to the regulations in (43 CFR 185.35, 185.36.)

5. The State of Oregon has waived the preference right of application granted to certain States by subsection (c) of section 2 of the Act of August 27, 1958 (72 Stat. 928; 43 U.S.C. 851, 852).

Inquiries should be addressed to the Manager, Land Office, Bureau of Land Management, Portland, Oregon.

JOHN A. CARVER, Jr.,
Assistant Secretary of the Interior.

JUNE 14, 1963.

[F.R. Doc. 63-6474; Filed, June 19, 1963; 8:48 a.m.]

[Public Land Order 3105]

[Nevada 045117]

NEVADA

Revoking Air Navigation Site Withdrawal No. 203

By virtue of the authority contained in Section 4 of the Act of May 24, 1928 (45 Stat. 729; 49 U.S.C. 214), it is ordered as follows:

The departmental order of May 27, 1943, which withdrew the following-described lands as Air Navigation Site Withdrawal No. 203, is hereby revoked:

MOUNT DIABLO MERIDIAN

T. 12 N., R. 36 E.,
Sec. 5, that part west of west line of right-of-way of State highway;
Sec. 6, S½SE¼;
Sec. 7, N½NE¼;
Sec. 8, that part of N½ west of west line of right-of-way of State highway, and N½SW¼.

The areas described aggregate approximately 734 acres.

The lands have been conveyed to the County of Nye, Nevada under the provisions of section 16 of the Federal Airport Act of May 13, 1946 (60 Stat. 179; 49 U.S.C. 1115).

JOHN A. CARVER, Jr.,
Assistant Secretary of the Interior.

JUNE 14, 1963.

[F.R. Doc. 63-6475; Filed, June 19, 1963; 8:48 a.m.]

Proposed Rule Making

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[7 CFR Parts 1001, 1002, 1003, 1004, 1006, 1007, 1010, 1014, 1015, 1016]

MILK IN GREATER BOSTON, MASS.; NEW YORK-NEW JERSEY; PHILADELPHIA, PA.; SOUTHEASTERN NEW ENGLAND; SPRINGFIELD, MASS.; UPPER CHESAPEAKE BAY; WASHINGTON, D.C.; WORCESTER, MASS.; WILMINGTON, DEL.; AND CONNECTICUT MARKETING AREAS

Notice of Proposed Suspension of Certain Provisions of Orders

Notice is hereby given that, pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.), the suspension of certain provisions of the orders regulating the handling of milk in the Greater Boston, Mass.; New York-New Jersey; Philadelphia, Pa.; Southeastern New England; Springfield, Mass.; Upper Chesapeake Bay; Washington, D.C.; Worcester, Mass.; Wilmington, Del.; and Connecticut marketing areas is being considered for the months of July and August 1963.

The provisions proposed to be suspended would reduce the surplus milk prices in such markets (Class III price in New York-New Jersey and Class II prices in other markets) eight cents per hundredweight under the levels which would otherwise prevail in such months.[1]

The specific provisions proposed to be suspended for July are:

1. In § 1001.41(b), § 1002.40(e)(2), § 1003.50(b)(2), § 1004.50(b)(2), § 1014.40(b)(2), § 1015.40(b)(2) and § 1016.50(b)(2), the words "for the applicable month".

2. In § 1001.41(b) all of the table except the words "Amount", "(cents)" and the figure "00".

3. In § 1002.40(e)(2) all of the table except the words "Amount", "(cents)" and the figure "00".

4. In § 1003.50(b)(2) all of the table except the word "Amount" and the figure "+.02".

5. In § 1004.50(b)(2) all of the table except the words "Amount", "(cents)" and the figure "+.08".

6. In § 1014.40(b)(2) all of the table except the word "Amount" and the figure "+.058".

7. In § 1015.40(b)(2) all of the table except the word "Amount" and the figure "+.058".

8. In § 1016.50(b)(2) all of the table except the word "Amount" and the figure "+.02".

The specific provisions proposed to be suspended for August are:

1. In § 1001.41(b), § 1002.40(e)(2), § 1003.50(b)(2), § 1004.50(b)(2), § 1014.40(b)(2), § 1015.40(b)(2) and § 1016.50(b)(2), the words "for the applicable month".

2. In § 1001.41(b) all of the table except the words "Amount", "(cents)" and the figure "+07".

3. In § 1002.40(e)(2) all of the table except the words "Amount", "(cents)" and the figure "+07".

4. In § 1003.50(b)(2) all of the table except the word "Amount" and the figure "+.09".

5. In § 1004.50(b)(2) all of the table except the words "Amount", "(cents)" and the figure "+15".

6. In § 1014.40(b)(2) all of the table except the word "Amount" and the figure "+.128".

7. In § 1015.40(b)(2) all of the table except the word "Amount" and the figure "+.128".

8. In § 1016.50(b)(2) all of the table except the word "Amount" and the figure "+.09".

At the joint 10 market public hearing on Class I and surplus prices held at New York City during the period May 6–23, 1963, representatives of producers and handlers urged that emergency action be taken on various proposals to reduce surplus milk prices for July and August 1963.

Subsequent to the recent hearing, the Department received a request from several cooperative associations in the New York-New Jersey market for suspension action which would have the effect of decreasing the Class III price for July and August only insofar as such price applies to certain specified products included in Class III. However, it is not mechanically feasible to limit the application of any such suspension only to a portion of the products included in such class.

In lieu of the various requests presented, the Department is considering the above suspension action for the months of July and August 1963.

All persons who desire to submit written data, views, or arguments in connection with the proposed suspension should file the same with the Hearing Clerk, Room 112, Administration Building, United States Department of Agriculture, Washington 25, D.C., not later than three days from the date of publication of this notice in the FEDERAL REGISTER. All documents filed should be in quadruplicate.

Signed at Washington, D.C., on June 17, 1963.

LINLEY E. JUERS,
Acting Deputy Administrator, Regulatory Programs, Agricultural Marketing Service.

[F.R. Doc. 63-6509; Filed, June 19, 1963; 8:56 a.m.]

[1] No specific suspension action is necessary in the Springfield, Worcester and Wilmington marketing areas since the Springfield and Worcester Class II prices are tied directly to the Greater Boston Class II price and the Wilmington Class II price is tied directly to the Philadelphia Class II price.

[7 CFR Part 1138]

[Docket No. AO-335-A2]

MILK IN THE RIO GRANDE VALLEY MARKETING AREA

Notice of Hearing on Proposed Amendments to Tentative Marketing Agreement and Order

Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.), and the applicable rules of practice and procedure governing the formulation of marketing agreements and marketing orders (7 CFR Part 900), notice is hereby given of a public hearing to be held at the Schines Western Skies Hotel, 13400 Central Avenue South East, Albuquerque, New Mexico, beginning at 10:00 a.m. local time, on June 24, 1963, with respect to proposed amendments to the tentative marketing agreement and to the order, regulating the handling of milk in the Rio Grande Valley marketing area.

The public hearing is for the purpose of receiving evidence with respect to the economic and emergency marketing conditions which relate to the proposed amendments, hereinafter set forth, and any appropriate modifications thereof, to the tentative marketing agreement and to the order.

The proposed amendments, set forth below, have not received the approval of the Secretary of Agriculture.

Proposed by the New Mexico Milk Producers Association and the Dairy Farmers Association:

Proposal No. 1. Amend § 1138.7(b) to read as follows:

(b) Diverted from a pool plant to a nonpool plant for the account of the diverting handler subject to the following conditions:

(1) A cooperative association may divert for its account the milk of any member producer whose milk is received at a pool plant for at least three days during the month without limit during such month: *Provided,* That the total quantity of milk so diverted does not exceed 20 percent in the months of March, April, May and June, and 10 percent in other months of its member producer milk received by all pool plants during the month: *And provided further,* That if this percentage limitation is exceeded, diversions in excess of such percentages shall not be considered producer milk and the diverting cooperative shall specify the dairy farmers whose milk is ineligible as producer milk.

(2) A handler in his capacity as the operator of a pool plant may divert for his account the milk of any producer, other than a member of a cooperative association which has diverted milk pursuant to subparagraph (1) of this paragraph, whose milk is received at his pool plant for at least three days during the month, without limit during such month: *Provided,* That the total quantity of milk so diverted does not exceed 20 percent in the months of March, April, May, and June, and 10 percent in other months of milk received at such pool plant during the month from producers who are not members of a cooperative association which has diverted milk pursuant to subparagraph (1) of this paragraph: *And provided further,* That if this percentage limitation is exceeded, diversions in excess of such percentage shall not be considered producer milk and the diverting handler shall specify the dairy farmers whose milk is ineligible as producer milk.

(3) For purposes of the requirements of § 1138.10, milk diverted for the account of the operator of a pool plant shall be included in the receipts of the pool plant from which diverted; and

(4) For purposes of location adjustments pursuant to §§ 1138.52 and 1138.81, milk diverted shall be considered to have been received at the location of the nonpool plant to which diverted.

Proposed by the Milk Marketing Orders Division, Agricultural Marketing Service:

Proposal No. 2. Make such changes as may be necessary to make the entire marketing agreement and the order conform with any amendments thereto that may result from this hearing.

Copies of this notice of hearing and the order may be procured from the Market Administrator, Earl C. Born, Post Office Box 8636, 227 San Pedro NE., Albuquerque, New Mexico, or from the Hearing Clerk, Room 112, Administration Building, United States Department of Agriculture, Washington 25, D.C., or may be there inspected.

Signed at Washington, D.C., on June 18, 1963.

LINLEY E. JUERS,
Acting Deputy Administrator, Regulatory Programs, Agricultural Marketing Service.

[F.R. Doc. 63-6535; Filed, June 19, 1963; 8:55 a.m.]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 121, 146]

FOOD ADDITIVES PERMITTED IN ANIMAL FEED OR ANIMAL FEED SUPPLEMENTS

Antibiotics for Growth Promotion and Feed Efficiency; Notice of Proposal To Amend Regulations

Following publication of § 121.225 *Antibiotics for growth promotion and feed efficiency,* questions were raised that showed a general misunderstanding of the scope intended by § 146.26 of the antibiotic regulations. The Commissioner of Food and Drugs has considered these questions and other relevant data, and has concluded that these regulations should be amended to conform to the food additives amendment of 1958 and to establish the levels of antibiotics that may be safely used for growth promotion and increasing feed efficiency and to clarify what is encompassed by the existing regulations.

Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(d), 72 Stat. 1787; 21 U.S.C. 348(d)), and under the authority delegated to the Commissioner by the Secretary of Health, Education, and Welfare (25 F.R. 8625), it is proposed to amend the antibiotic and food additive regulations as follows:

1. By revoking § 121.206 *Oleandomycin* and by incorporating the provisions of that section in § 121.225, as paragraph (i):

2. By changing the introduction to paragraph (a) of § 121.225, and paragraph (a) (3) (ii) of that section to read as set forth below, and by adding to paragraph (a) (3) new subdivisions (v) and (vi), as follows:

§ 121.225 Antibiotics for growth promotion and feed efficiency.

* * * * *

(a) *Procaine penicillin.* Procaine penicillin as follows:

* * * * *

(3) * * *

(ii) In the feed of quail not over 5 weeks of age, in an amount not less than 5 grams nor more than 20 grams per ton of finished feed.

* * * * *

(v) With bacitracin, bacitracin methylene disalicylate, manganese bacitracin, or zinc bacitracin in the feed of swine, in an amount not less than 2.50 grams of penicillin and not less than 7.50 grams of bacitracin nor more than 50 grams of the combination per ton of finished feed.

(vi) With streptomycin in the feed of swine, in an amount not less than 3 grams of penicillin and not less than 15 grams of streptomycin nor more than 50 grams of the combination per ton of finished feed.

3. By changing the introduction to paragraph (b) and paragraph (b) (3) (ii) of § 121.225 to read as set forth below, and by adding to paragraph (b) (3) new subdivisions (iv) and (v), as follows:

(b) *Bacitracin.* Bacitracin as follows:

* * * * *

(3) * * *

(ii) In the feed of quail not over 5 weeks of age, in an amount not less than 5 grams nor more than 20 grams per ton of finished feed.

* * * * *

(iv) In the feed of swine, in an amount not less than 10 grams nor more than 50 grams per ton of finished feed.

(v) With procaine penicillin as provided in paragraph (a) (3) (v) of this section.

4. By changing the introduction to paragraph (c) of § 121.225 to read as set forth below, and by adding to paragraph (c) (3) new subdivisions (iv), (v), and (vi), as follows:

(c) *Zinc bacitracin.* Zinc bacitracin as follows:

* * * * *

(3) * * *

(iv) In the feed of quail not over 5 weeks of age, in an amount not less than 5 grams nor more than 20 grams per ton of finished feed.

(v) In the feed of swine, in an amount not less than 10 grams nor more than 50 grams per ton of finished feed.

(vi) With procaine penicillin as provided in paragraph (a) (3) (v) of this section.

5. By changing the introduction to paragraph (d) of § 121.225 to read as set forth below and by adding to paragraph (d) (3) new subdivisions (iii), (iv), and (v), as follows:

(d) *Bacitracin methylene disalicylate.* Bacitracin methylene disalicylate as follows:

* * * * *

(3) * * *

(iii) In the feed of quail not over 5 weeks of age, in an amount not less than 5 grams nor more than 20 grams per ton of finished feed.

(iv) In the feed of swine, in an amount not less than 10 grams nor more than 50 grams per ton of finished feed.

(v) With procaine penicillin as provided in paragraph (a) (3) (v) of this section.

6. By changing the introduction to paragraph (e) of § 121.225 to read as set forth below, and by adding to subparagraph (3) new subdivisions (iii) and (iv), as follows:

(e) *Streptomycin.* Streptomycin as follows:

* * * * *

(3) * * *

(iii) With procaine penicillin as provided in paragraph (a) (3) (vi) of this section.

(iv) In the feed of swine, in an amount not less than 15 grams nor more than 50 grams per ton of finished feed.

7. By changing the introduction to paragraph (f) of § 121.225 and paragraph (f) (3) (ii) to read as set forth below, and by adding to paragraph (f) (3) new subdivisions (iii), (iv), (v), and (vi), as follows:

(f) *Chlortetracycline.* Chlortetracycline as follows:

* * * * *

(3) * * *

(ii) In the feed of mink, in an amount not less than 20 grams nor more than 50 grams per ton of finished feed, and also as an aid in increasing pelt size.

(iii) In the feed of swine, in an amount not less than 10 grams nor more than 50 grams per ton of finished feed.

(iv) In the feed of lambs and growing sheep, in an amount not less than 20 grams nor more than 50 grams per ton of finished feed.

(v) In the feed of calves, in an amount not less than 25 milligrams per head per day nor more than 70 milligrams per head per day in finished feed.

(vi) In the feed of growing cattle, in an amount equal to 70 milligrams per head per day in finished feed.

8. By deleting § 121.225(f)(4).

9. By changing the introduction to paragraph (g) of § 121.225 to read as set forth below and by adding to paragraph (g)(3) new subdivisions (iv), (v), and (vi), as follows:

(g) *Manganese bacitracin.* Manganese bacitracin as follows:

* * * * *

(3) * * *

(iv) In the feed of quail not over 5 weeks of age, in an amount not less than 5 grams nor more than 20 grams per ton of finished feed.

(v) With procaine penicillin as provided in paragraph (a)(3)(v) of this section.

(vi) In the feed of swine, in an amount not less than 10 grams nor more than 50 grams per ton of finished feed.

10. By adding to § 121.225 the following new paragraphs:

(i) *Oleandomycin.* Oleandomycin as follows:

(1) Oleandomycin is the antibiotic substance produced by the growth of Streptomyces antibioticus or the same antibiotic substance produced by any other means, and for the purposes of this paragraph refers to oleandomycin or feed-grade oleandomycin.

(2) The quantities of the antibiotics referred to in this paragraph refer to activities equivalent to those of the appropriate antibiotic master standard and may be adsorbed upon a suitable carrier vehicle that is not a food additive or which is provided for by regulation in this chapter.

(3) It is used or intended for use:

(i) In the feed of chickens and turkeys, in an amount not less than 1 gram nor more than 2 grams per ton of finished feed.

(ii) With oxytetracycline hydrochloride in the feed of swine containing 2 grams of oleandomycin and 8 grams of oxytetracycline hydrochloride per ton of finished feed.

Pursuant to section 507 of the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463 as amended; 21 U.S.C. 357), it is proposed to amend the antibiotic regulations as follows:

11. By changing § 146.13 to read as follows:

§ 146.13 Manganese bacitracin medicated animal feed.

Animal feed containing manganese bacitracin powder oral veterinary, with or without added suitable vitamin substances, shall be exempt from the requirements of sections 502(1) and 507 of the act when used in the amounts and for the purposes indicated in § 121.225 of this chapter.

12a. By changing the section heading and the introduction to § 146.26 to read:

§ 146.26 Animal feed containing certifiable antibiotic drugs.

Animal feed containing penicillin, streptomycin, chlortetracycline, bacitracin, feed grade zinc bacitracin, or bacitracin methylene disalicylate or any permitted combination of two or more of these, with or without added suitable vitamin substances, shall be exempt from the requirements of sections 502(1) and 507 of the act when used in accordance with § 121.225 of this chapter, and under the conditions set forth in any one of the following paragraphs of this section:

b. By changing § 146.26(b)(46), (47), and (48) to read as follows:

(46) It is a milk feed containing chlortetracycline, in the amounts and for the purposes indicated in § 121.225 of this chapter, and its labeling bears adequate directions and warnings for such use.

(47) It is a pheasant feed containing bacitracin, zinc bacitracin, or bacitracin methylene disalicylate and penicillin, in the amounts and for the purposes indicated in § 121.225 of this chapter, and its labeling bears adequate directions and warnings for such use.

(48) It is a quail feed containing bacitracin and penicillin, in the amounts and for the purposes indicated in § 121.225 of this chapter, and its labeling bears adequate directions and warnings for such use.

* * * * *

The Commissioner of Food and Drugs hereby offers an opportunity to any interested person to submit views and comments on this proposal within 30 days from the date of publication of this notice in the FEDERAL REGISTER. Such views and comments should be submitted in triplicate and addressed to the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington 25, D.C.

Dated: April 12, 1963.

GEO. P. LARRICK,
Commissioner of Food and Drugs.

[F.R. Doc. 63-6487; Filed, June 19, 1963; 8:51 a.m.]

FEDERAL AVIATION AGENCY

[14 CFR Part 4b]

[Notice 63-21; Docket No. 1797]

TRANSPORT CATEGORY AIRPLANES

Revision of the Flutter, Deformation, and Vibration Requirements

Notice is hereby given that there is under consideration a proposal to amend § 4b.308 of Part 4b of the Civil Air Regulations to: (1) require that the dynamic evaluation of the airplane take into account elastic, inertia, and aerodynamic forces associated with rotations and displacements of the plane of the propeller; (2) require that the airplane, under specified conditions, remain free from hazardous flutter, vibration, and divergence after any reasonably probable single structural failure or equipment malfunction; and (3) make related minor revisions, including editorial revisions for clarification. Manufacturers and operators of transport category airplanes may be affected by the proposed amendment.

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Notice or Docket number and be submitted in duplicate to the Federal Aviation Agency, Office of the General Counsel: Attention Rules Docket, Room A-103, 1711 New York Avenue NW., Washington 25, D.C. All communications received on or before August 19, 1963, will be considered by the Administrator before taking action on the proposed rule. The proposals contained in this notice may be changed in the light of comments received. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons.

Regulations dealing specifically with flutter, deformation, and vibration on transport category airplanes were first introduced when Part 04 (later designated as Part 4b) became effective on November 9, 1945. These regulations evolved into currently effective § 4b.308 with the adoption of two substantive revisions, as follows: (1) effective March 5, 1952, the requirement that freedom from flutter and divergence be demonstrated at all speeds up to 1.2 V_D was amended to permit this demonstration at speeds up to a value less than 1.2 V_D if the characteristics of the airplane are such that it would be unlikely to attain a speed of 1.2 V_D and if it is shown that a proper margin of damping exists at speed V_D; and (2) effective October 1, 1959, a provision was added requiring that, if control surface flutter dampers are used for flutter prevention, the flutter damper system be of such design that a single failure will not preclude continued safe flight of the airplane at any speed up to V_D.

During the period between 1945 and 1955, § 4b.308 and predecessor regulations were generally effective in insuring freedom from flutter and divergence in transport category airplanes, despite the absence of a provision requiring an investigation of the influence of a single structural failure on flutter stability. A reasonable margin of safety was evidently provided by reason of the required demonstration that the airplane be free from flutter and divergence at speeds up to 1.2 V_D, over the critical ranges of the pertinent parameters.

Subsequently, several reported instances of tab flutter on a transport category airplane led to adoption of the provision in currently effective § 4b.320 (a) which, by cross-reference to § 4b.308, requires that tab control systems be free from hazardous flutter after disconnection or failure of any element at speeds up to V_C. This provision became effective on March 13, 1956.

In general, applicants have resorted to analyses in showing compliance with the provisions of § 4b.308 and predecessor

regulations, supplemented in some cases by flight flutter tests on the prototype airplane. Such analyses (which have steadily improved in scope and precision with advances in the state of the art) have in the past taken into account, for propeller-driven airplanes, the mass of the engine-propeller combination and the natural frequency of vibration of its suspension, but not the elastic, inertia, and aerodynamic forces associated with the rotations and displacements of the propeller plane. These forces, experts on flutter analysis then agreed, had no significant effect on wing flutter stability.

During 1959 and 1960 two fatal accidents, both involving a civil four-engine turboprop airplane, focused particular attention on the hazards associated with aeroelastic instabilities in transport category airplanes. An exhaustive investigation into the cause of these accidents, and associated engineering studies by both industry and government experts, have indicated that the various forces associated with the rotations and displacements of the plane of the propeller must be considered in evaluating the flutter and divergence stability of transport category airplanes. The oscillatory motion of the plane of the propeller may itself become unstable, or diverge, or may contribute to instability of the wing. For these reasons, it is being proposed to amend § 4b.308(a) by adding a requirement that the dynamic evaluation of the airplane include consideration of the effect of significant elastic, inertia, and aerodynamic forces associated with rotations and displacements of the plane of the propeller.

The provisions of currently effective § 4b.308(a) are limited in scope in that they prescribe freedom from flutter and divergence for wing and tail units only; whereas it is well known that the higher speeds of modern transport category airplanes may introduce flutter or divergence in other portions of the airplane. To insure that tests or analyses take this possibility into account, it is proposed that the wording in § 4b.308(a) be amended to prescribe freedom from flutter and divergence for all portions of the airplane.

In the course of past application of the term "proper margin of damping" in currently effective § 4b.308(a), the Agency has indicated that the margin is acceptable if a satisfactory damping coefficient exists for all potential flutter modes at all speeds up to V_D, and if no large and rapid reduction in damping with increased speed is indicated upon approaching V_D. In this regard, it is proposed to amend § 4b.308(a) to clearly state what is meant by the term "proper margin of damping."

The previously mentioned government-industry studies have also disclosed that severe degradation of the wing's aeroelastic properties could result from failure of a structural member (including those which form part of the engine itself in the case of turboprop engines) which supports the engine-propeller combination, or from failure of the propeller control system such that overspeeding of the propeller occurs.

In view of these findings, and in view of past findings indicating that failures in tab and damper control elements may result in flutter, the Agency believes there is a need for a comprehensive set of requirements dealing with the effect of probable failures on flutter stability. The Agency has noted, for example, that hazardous flutter may be induced by any failure reducing the rigidity of irreversible main control systems which are fitted with power boost; by a failure in the power boost itself; by a failure or malfunction of an automatic flight control system; or by failure or partial failure of single principal structural elements. It is therefore proposed to add a new paragraph (d) to § 4b.308 to require that the airplane be free of flutter, after specified failures or malfunctions, at all speeds up to V_D.

This proposal is subject to the FAA Recodification Program. The final rule, if adopted, may be in a recodified form; however, the recodification itself will not alter the substantive contents proposed herein.

In consideration of the foregoing, it is proposed to amend Part 4b of the Civil Air Reglations as hereinafter set forth:

1. By amending § 4b.308(a) to read as follows:

§ 4b.308 Flutter, deformation, and vibration.

* * * * *

(a) *Flutter and divergence prevention.* The airplane shall be designed to be free from flutter and divergence (i.e., unstable structural distortion due to aerodynamic loading) at all speeds up to 1.2 V_D. A smaller margin above V_D shall be acceptable if the characteristics of the airplane (including the effects of compressibility) render a speed of 1.2 V_D unlikely to be achieved, and if it is shown that a satisfactory damping coefficient exists at all speeds up to V_D and that there is no large and rapid reduction in damping as V_D is approached. In the absence of more accurate data, the terminal velocity in a dive of 30 degrees to the horizontal shall be acceptable as the maximum speed likely to be achieved. If concentrated balance weights are used on control surfaces, their effectiveness and strength, including supporting structure, shall be substantiated. The dynamic evaluation of the airplane shall include an investigation of the significant elastic, inertia, and aerodynamic forces associated with the rotations and displacements of the plane of the propeller.

2. By amending § 4b.308 by adding a new paragraph (d) to read as follows:

(d) *Fail safe criteria.* It shall be shown, by analysis or tests, that the airplane will remain free from such flutter, divergence, or vibrations as would preclude safe flight, at all speeds up to V_D, after each of the failures, malfunctions, and adverse conditions stated in subparagraphs (1) through (7) of this paragraph, and after any other reasonably probable single failure, malfunction, or adverse condition affecting flutter, divergence, or vibration; except that, if the failure, malfunction, or adverse condition is simulated during flight tests to show compliance with this paragraph, the maximum speed investigated need not exceed V_{FC} when it is shown, by correlation of the flight test data with other test data or analysis, that hazardous flutter, divergence, or vibration will not occur at all speeds up to V_D. The structural failures described in subparagraphs (1) and (2) of this paragraph need not be considered in showing compliance with this paragraph if engineering data verifies that the probability of their occurrence is negligible. Such engineering data shall substantiate, by test or analysis, that the structural element is designed with conservative static strength margins for all ground and flight loading conditions specified in this part, and with fatigue strength sufficient for the loading spectrum expected in service.

(1) Failure of any single element of the structure supporting any engine, independently mounted propeller shaft, large auxiliary power unit, or large externally-mounted aerodynamic body such as an external fuel tank.

(2) Any single failure of the engine structure on turboprop airplanes.

(3) Any single propeller feathered.

(4) Each of the failures described in subparagraphs (1) and (2) of this paragraph, paired with the feathering of any single propeller.

(5) Any single propeller rotating at the highest likely overspeed.

(6) Failure of each principal structural element for which compliance with the provisions of § 4b.270(b) is required.

(7) Failure, malfunction, or disconnection of any single element in the main flight control system (including automatic flight control systems, if installed), in any tab control system, or in any flutter damper connected to a control surface or tab. (See also § 4b.612 (d)(4).)

These regulations are proposed under the authority of sections 313(a), 601, and 603 of the Federal Aviation Act of 1958 (72 Stat. 752, 775, 776; 49 U.S.C. 1354, 1421, 1423).

Issued in Washington, D.C., on June 13, 1963.

G. S. MOORE,
Director,
Flight Standards Service.

[F.R. Doc. 63-6465; Filed, June 19, 1963; 8:46 a.m.]

FEDERAL COMMUNICATIONS COMMISSION

[47 CFR Part 3]

[Docket No. 15083]

ADVERTISING ON STANDARD, FM, AND TELEVISION BROADCAST STATIONS

Order Extending Time for Filing Comments and Reply Comments

1. In a notice of proposed rule making released in the instant proceeding on May 17, 1963, the Commission invited

comments to be filed not later than July 1, 1963, and reply comments not later than July 15, 1963.

2. In a Request for Extension of Time in Which to File Comments filed June 6, 1963, the National Association of Broadcasters asks that the time for filing comments be extended from July 1, 1963, to November 1, 1963.

3. In support thereof it is stated that the limitation of advertising time as proposed in this proceeding raises questions of statutory and constitutional law and considerations of national public policy thorough study and research of which will require more time than that allotted.

4. In addition, it is pointed out that the Commission recognized that cross-the-board application of the NAB code to all stations might not be appropriate, and therefore invited detailed comments from persons with situations that might warrant special treatment. It is alleged that more time for filing comments is necessary if such comments are to be meaningful and helpful.

5. Another reason given to buttress the request is that the industry is presently engaged in the preparation of comments in other important proceedings presently pending before the Commission, such as Docket No. 15040, dealing with the broadcast of horse racing information, in which comments are due July 1, 1963, and Docket No. 15084, dealing with the revision of AM assignment standards and the relationship between the AM and FM broadcast services, in which comments are due on July 17, 1963.

6. Finally, it is suggested that consideration be given to the fact that the months of July and August are traditional vacation months for both government and industry, and that the gravity of the proposal requires full attention of many personnel who ordinarily would be on vacation during this period.

7. We are of the opinion that the request has merit and that an extension of time should be granted in order to permit the industry to supply the Commission with meaningful material that will be helpful in its deliberations concerning the subject matter of this proceeding. However, we are also of the opinion that the problem is one which merits prompt consideration. We believe that both of these objectives can be met by an extension of time for filing comments from July 1, 1963, to September 16, 1963, and by a corresponding extension of the reply comment filing date from July 15, 1963, to September 30, 1963.

8. In view of the foregoing: *It is ordered,* This 13th day of June, 1963, That the time for filing comments in this proceeding is extended from July 1, 1963, to September 16, 1963, and the time for filing reply comments is extended from July 15, 1963, to September 30, 1963; and that the Request for Extension of Time in Which to File Comments filed by the National Association of Broadcasters is granted insofar as it is consistent with the action taken herein and in other respects is denied.

9. This action is taken pursuant to authority found in sections 4(i), 5(d)(1) and 303(r) of the Communications Act of 1934, as amended, and Section 0.241(d)(8) of the Commission rules.

Released: June 17, 1963.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

[F.R. Doc. 63-6496; Filed, June 19, 1963; 8:53 a.m.]

Notices

DEPARTMENT OF THE TREASURY

Comptroller of the Currency

NATIONAL BANK AND TRUST COMPANY AT CHARLOTTESVILLE AND STATE BANK OF MADISON, INC.

Notice of Decision Granting Application To Merge

On April 12, 1963, the National Bank and Trust Company at Charlottesville, Charlottesville, Virginia, and the State Bank of Madison, Inc., Madison, Virginia, applied to the Comptroller of the Currency for permission to merge under the charter and with the title of the former.

On June 3, 1963, the Comptroller of the Currency granted this application, effective on or after June 8, 1963.

Copies of this decision are available on request to the Comptroller of the Currency, Washington 25, D.C.

Dated: June 14, 1963.

[SEAL] A. J. FAULSTICH,
Administrative Assistant to the Comptroller of the Currency.

[F.R. Doc. 63-6479; Filed, June 19, 1963; 8:48 a.m.]

Bureau of Customs

[T.D. 55919]

COTTON TEXTILES FROM THE REPUBLIC OF CHINA

Revision of Previously Published Levels of Restraint

JUNE 17, 1963.

There is published below a letter of June 7, 1963, from the Chairman, President's Cabinet Textile Advisory Committee, which reduces the levels of restraint on Categories 9, 31, and 50 of cotton textiles produced or manufactured in the Republic of China which may be entered in the United States during the periods specified therein. This letter supplements the letter of December 20, 1962, published in T.D. 55802 (28 F.R. 324).

These reductions offset the increase allowed in Category 51. See T.D. 55867 (28 F.R. 3285).

Collectors of customs and appraisers of merchandise have been advised of these changes and have been instructed to bring them to the attention of all brokers, importers, and others concerned.

[SEAL] N. G. STRUB,
Acting Commissioner of Customs.

THE SECRETARY OF COMMERCE
PRESIDENT'S CABINET
TEXTILE ADVISORY COMMITTEE
Washington 25, D.C., June 7, 1963.

COMMISSIONER OF CUSTOMS,
DEPARTMENT OF THE TREASURY,
Washington, D.C.

DEAR MR. COMMISSIONER: On March 15, 1963, the Chairman of the President's Cabinet Textile Advisory Committee wrote you directing that the levels of restraint applicable to the entry of cotton textile goods, produced or manufactured in the Republic of China, in Category 51 into the United States for consumption and withdrawal from warehouse for consumption for the period November 13, 1962, through September 30, 1963, be increased by designated amounts. The adjusted amounts allowed to be entered during specified periods were set forth in that letter.

Pursuant to negotiations with representatives of the Government of the Republic of China, reductions in existing levels of restraint have been agreed upon in Categories 9, 31, and 50 to offset the increase allowed in Category 51. Existing levels of restraint applicable to these categories are set forth as an enclosure to our letter to you dated December 20, 1962 (published by you in the FEDERAL REGISTER of January 11, 1963, 28 F.R. 324).

The reduced levels are as follows:

Category, Period, and Amount[1]

9; Nov. 13, 1962, through June 30, 1963; no change.
9; Nov. 13, 1962, through Sept. 30, 1963; 10,583,676 sq. yds.
31; Nov. 13, 1962, through June 30, 1963; 257,992 units.
31; Nov. 13, 1962, through Sept. 30, 1963; 324,720 units.
50; Nov. 13, 1962, through June 30, 1963; 128,101 dozen.
50; Nov. 13, 1962, through Sept. 30, 1963; 128,101 dozen.

This adjusted schedule shall be effective immediately. The detailed descriptions of Categories 9, 31, and 50 in terms of Schedule A numbers and U.S.I.D.A. numbers were attached to our letter of October 22, 1962, to you, published in the FEDERAL REGISTER on November 1, 1962. You are requested to publish this letter in the FEDERAL REGISTER.

Sincerely yours,

LUTHER H. HODGES,
Secretary of Commerce, and Chairman, President's Cabinet Textile Advisory Committee.

[F.R. Doc. 63-6506; Filed, June 19, 1963; 8:56 a.m.]

[1] These amounts are adjustments to existing levels of restraint for the period Nov. 13, 1962, through Sept. 30, 1963, and are effective retroactively to Nov. 13, 1962.

DEPARTMENT OF JUSTICE

Office of Alien Property

[Dissolution Order No. 132]

AMERICAN LURGI CORP.

Order of Dissolution and Distribution of Assets

Whereas, by virtue of the issuance of Vesting Order No. 41, executed June 30, 1942 (7 F.R. 5079, July 4, 1942) and Executive Order 9788, dated October 14, 1946 (11 F.R. 11981, October 15, 1946), the Attorney General of the United States (hereinafter referred to as "Attorney General") is the owner of 150 shares of $10 par value common stock and 600 shares of $100 par value preferred stock of American Lurgi Corporation (hereinafter referred to as "AmLurgi"), a New York corporation, said shares being all of the issued and outstanding capital stock of AmLurgi; and

Whereas, a Certificate of Dissolution of AmLurgi was issued by the Secretary of State of the State of New York on November 26, 1946, certifying to the dissolution of AmLurgi; and

Whereas, AmLurgi has been substantially liquidated;

Now, therefore, under the authority of the Trading with the Enemy Act, as amended, and Executive Orders 9095, as amended, and 9788, and pursuant to law, the undersigned, after investigation:

1. Finding that the assets of AmLurgi consist of cash in bank in the amount of $14,552.02;

2. Finding that the liabilities of AmLurgi consist of

(a) A recorded account payable of $12,578.56 to the Attorney General for services rendered to or on behalf of AmLurgi from date of vesting to final winding up of the corporation,

(b) A balance of $13,211.70 owing to the Attorney General under Vesting Order 4271,

(c) A balance of $3,898.79 owing to the Attorney General under Vesting Order 4276;

3. Having determined that it is in the national interest of the United States that AmLurgi be dissolved, that its affairs be wound up and that its assets be distributed;

Hereby orders, That the officers and directors of AmLurgi (and their successors, or any of them) wind up the affairs of AmLurgi and distribute the assets of AmLurgi as follows:

I. They shall first pay all current expenses and necessary charges, if any, in effecting the dissolution of AmLurgi and winding up its affairs;

II. They shall then pay all known Federal, State and local taxes and fees, if any, owed by or accrued against AmLurgi;

III. They shall then pay the Attorney General $12,578.56 in full payment of his charges, as an administrative expense, for services rendered to or on behalf of AmLurgi;

IV. They shall then pay over, assign and deliver to the Attorney General all remaining cash funds and other assets, including after discovered assets, for application pro rata on the unpaid balances of $13,211.70 and $3,898.79 owing under Vesting Orders 4271 and 4276; and

Further orders, That nothing herein set forth shall be construed as prejudicing any rights under the Trading with the Enemy Act, as amended, of any person who may have a claim against

AmLurgi to file such claim with the Attorney General against any funds or property received by the Attorney General hereunder; *Provided, however,* That nothing herein contained shall be construed as creating additional rights in such person; *Providing further,* That any such claim against AmLurgi shall be filed with or presented to the Attorney General within the time and in the form and manner prescribed for such claims by the Trading With the Enemy Act, as amended, and applicable regulations and orders issued pursuant thereto; and

Further orders, That all actions taken and acts done by the officers and directors of AmLurgi pursuant to this order and the directions contained herein shall be deemed to have been taken and done in reliance on and pursuant to section 5(b)(2) of the Trading With the Enemy Act, as amended (50 U.S.C. App. 5(b)(2)), and the acquittance and exculpation provided therein.

Executed at Washington, D.C. on June 12, 1963.

For the Attorney General.

[SEAL] PAUL V. MYRON,
Deputy Director,
Office of Alien Property.

[F.R. Doc. 63-6461; Filed, June 19, 1963; 8:45 a.m.]

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

STANDING ROCK AND FORT BERTHOLD INDIAN RESERVATIONS

Transfer of Land Records to Aberdeen Area Office

JUNE 14, 1963.

In accordance with 25 CFR 120 and pursuant to authority delegated by Amendment No. 49 to Secretarial Order 2508 (26 F.R. 11395), notice is hereby given that all source title documents and land records pertaining to trust or restricted Indian-owned land on the Standing Rock Indian Reservation in the States of North Dakota and South Dakota and the Fort Berthold Indian Reservation in the State of North Dakota, have been transferred from the City of Washington, D.C., to the Aberdeen Area Office, Bureau of Indian Affairs, 820 South Main Street, Aberdeen, South Dakota. Effective June 17, 1963, the Aberdeen Area Office will be the office for the maintenance of records for all such trust and restricted lands.

JOHN O. CROW,
Acting Commissioner.

[F.R. Doc. 63-6466; Filed, June 19, 1963; 8:46 a.m.]

Bureau of Land Management

[Classification No. 60; Amdt.]

ARIZONA

Small Tract Classification; Correction

In F.R. Document 63-5977, appearing at page 5586 of the issue for Thursday, June 6, 1963, paragraph 1 should read as follows:

1. Effective this date, paragraph 3 of Arizona Document No. 177, Small Tract Classification No. 60, appearing in 23 F.R. 1154 of February 22, 1958, is hereby amended to read as follows:

Dated: June 12, 1963.

MARTIN W. BUZAN,
Acting State Director.

[F.R. Doc. 63-6468; Filed, June 19, 1963; 8:47 a.m.]

ALASKA

Notice of Filing of Plat of Survey and Order Providing for Opening of Public Lands

JUNE 13, 1963.

1. Plats of survey described below will be officially filed in the Anchorage Land Office, Anchorage, Alaska, effective at 10:00 a.m., July 1, 1963.

FAIRBANKS MERIDIAN

T. 20 S., R. 10 W.,
Sec. 31: Lots 1-10, S½NE¼, NE¼NE¼, SE¼SW¼, SE¼;
Sec. 32: All;
Sec. 33: All.

Containing 1,831.55 acres.

T. 21 S., R. 10 W.,
Sec. 5: All;
Sec. 6: Lots 1-4, E½W½, E½.

Containing 1,276.20 acres.

2. This parcel of land lies in the Chulitna River Valley, in the vicinity of Colorado Station on the Alaska Railroad. The character of the land is rolling to steep along the river escarpments. The soil is, for the most part, thin, rocky and extremely swampy in much of the area. Timber is scattered to heavy first and second growth spruce, birch, aspen and cottonwood, with a dense covering of alder brush over a large portion of the area.

3. Subject to any existing valid rights, the provisions of existing withdrawals, and the requirements of applicable law, the above-described land is hereby opened to filing applications, selections and locations in accordance with the following: a. Applications and selections under the nonmineral public land laws may be presented to the Manager, Anchorage Land Office, beginning on the date of this order. Such applications, selections and offers will be considered as filed on the hour and respective dates shown for the various classes enumerated in the following paragraphs:

(1) Applications by persons having prior existing valid settlement rights, preference rights conferred by existing laws, or equitable claims subject to allowance and confirmation will be adjudicated on the facts presented in support of each claim or right. All applications presented by persons other than those referred to in this paragraph will be subject to the applications and claims mentioned in this paragraph.

(2) All valid applications and selections under the nonmineral pubilc land laws presented prior to 10:00 a.m. on July 1, 1963, will be considered as simultaneously filed at that hour. Rights under such applications and selections filed after that hour will be governed by the time of filing. The lands will also be open to mining location at that date and hour.

4. Persons claiming preference rights based upon valid settlement, statutory preference or equitable claims must enclose properly corroborated statements in support of their applications, setting forth all facts relevant to their claim. Detailed rules and regulations governing applications which may be filed pursuant to this notice can be found in Title 43 of the Code of Federal Regulations.

5. Applications for these lands, which shall be filed in the Land Office at Anchorage, Alaska, shall be acted upon in accordance with the regulations contained in § 295.8 of Title 43 of the Code of Federal Regulations to the extent such regulations are applicable. Applications under the homestead and homesite laws shall be governed by the regulations contained in Parts 64, 65 and 166 of Title 43 of the Code of Federal Regulations.

6. Inquiries concerning these lands shall be addressed to the Manager, Anchorage Land Office, Anchorage, Alaska.

WARNER T. MAY,
Manager.

[F.R. Doc. 63-6467; Filed, June 19, 1963; 8:47 a.m.]

[Classification No. 11]

NEVADA

Small Tract Classification; Amendment

Effective June 17, 1963 Federal Register Document 48-4828, filed June 1, 1948, is amended to permit direct sale for small tract purposes, at not less than appraised values, all of the lands described therein. Descriptions shown on supplemental plat of sections 4, 5 and 9, T. 32 S., R. 64 E., M.D.M., approved April 24, 1962 in part supersedes descriptions contained in the original order.

The lands shall not be subject to application under the Small Tract Act of June 1, 1938 (52 Stat. 609, 43 U.S.C. 682a-e), as amended, until it is so provided by an order to be issued by an authorized officer, opening the lands to sale. All valid applications filed prior to October 7, 1955 will be granted, as soon as possible, the preference right provided for by 43 CFR 257.5.

ROBERT T. WEBB,
Acting District Manager.

JUNE 17, 1963.

[F.R. Doc. 63-6469; Filed, June 19, 1963; 8:47 a.m.]

[NM 0397687 (Okla.)]

OKLAHOMA

Notice of Proposed Withdrawal and Reservation of Lands

JUNE 13, 1963.

The Forest Service, U.S. Department of Agriculture, has filed an application

Serial Number NM 0397687 (Oklahoma) for the withdrawal of the lands described below, from all forms of appropriation under the public land laws, subject to existing valid rights; excepting, however, the mineral leasing laws. The applicant desires the land for addition to the Rita Blanca National Grassland Area, to permit more efficient administration in the conservation of national resources.

For a period of 30 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal may present their views in writing to the undersigned officer of the Bureau of Land Management, Department of the Interior, P.O. Box 1251, Santa Fe, New Mexico.

If circumstances warrant it, a public hearing will be held at a convenient time and place, which will be announced.

The determination of the Secretary on the application will be published in the FEDERAL REGISTER. A separate notice will be sent to each interested party of record.

The lands involved in the application are:

CIMARRON MERIDIAN, OKLAHOMA

T. 1 S., R. 1 E.,
Sec. 1, Lots 1 and 2.
T. 1 S., R. 3 E.,
Sec. 1, Lots 1 and 2.
T. 1 S., R. 4 E.,
Sec. 1, Lots 1, 2 and 3;
Sec. 2, Lots 1 and 2;
Sec. 5, Lots 1, 2 and 3;
Sec. 6, Lots 1 and 2.
T. 1 S., R. 5 E.,
Sec. 5, Lots 2 and 3;
Sec. 6, Lots 1 and 2.

The areas described aggregate 395.95 acres.

CHESLEY P. SEELY,
State Director.

[F.R. Doc. 63-6470; Filed, June 19, 1963; 8:47 a.m.]

WASHINGTON

Notice of Filing of Washington State Protraction Diagram

Notice is hereby given that effective July 20, 1963, the following protraction diagram, approved January 8, 1963, is officially filed of record in the Washington Land Office. In accordance with Title 43, Code of Federal Regulations, this protraction will become the basic record for describing the land for all authorized purposes at and after 10 a.m. of the above effective date. Until this date and time, the diagram has been placed in the open files and is available to the public for information only.

WILLAMETTE MERIDIAN

WASHINGTON PROTRACTION DIAGRAM NO. 4

T. 31 N., R. 8 E.
T. 32 N., R. 8 E.,
Sec. 13: E½SE¼;
Sec. 14: W½;
Sec. 15: E½;
Sec. 19: E½;
Secs. 20, 21, 22, 23, 24: part;
Sec. 25 through Sec. 36.
T. 31 N., R. 9 E.
T. 32 N., R. 10 E.,
Sec. 10 through Sec. 15;
Sec. 22 through Sec. 28;
Sec. 33 through Sec. 36.

Copies of this diagram are for sale at the Washington State Land Office, Bureau of Land Management, Room 670 Bon Marche Building, Spokane 1, Washington.

—JOHN G. WALTERS,
Manager.

[F.R. Doc. 63-6471; Filed, June 19, 1963; 8:48 a.m.]

Office of the Secretary

CRUDE OIL, UNFINISHED OILS AND FINISHED PRODUCTS, OTHER THAN RESIDUAL FUEL OIL TO BE USED AS FUEL

Adjustments in Maximum Levels of Imports Into Puerto Rico

The maximum levels of imports into Puerto Rico of crude oil, unfinished oils and finished products, other than residual fuel oil to be used as fuel, established by Presidential Proclamation 3279, as amended, are modified pursuant to paragraph (c) of section 2 of the Proclamation to permit, during the period July 1, 1963 through December 31, 1963, 109,912 barrels per day in imports of crude oil and unfinished oils, and an additional 342 barrels per day in the imports of finished products, other than residual fuel oil to be used as fuel, to meet the increased demand in Puerto Rico and demand for export to foreign areas.

All non-Governmental holders of allocations of imports of finished products, other than residual fuel oil to be used as fuel, into Puerto Rico, have been canvassed with respect to their interest in supplying the increased requirements for finished products. With the exception of the Shell Oil Companies all others have stated that they have no interest. Accordingly, the allocation made to the Shell Oil Companies will be increased to permit them to import into Puerto Rico an additional 342 barrels daily of asphalt.

STEWART L. UDALL,
Secretary of the Interior.

JUNE 18, 1963.

[F.R. Doc. 63-6548; Filed, June 19, 1963; 8:57 a.m.]

DEPARTMENT OF AGRICULTURE

Office of the Secretary

MISSISSIPPI

Designation of Area for Emergency Loans

For the purpose of making emergency loans pursuant to section 321 of the Consolidated Farmers Home Administration Act of 1961 (7 U.S.C. 1961), it has been determined that in Pike County, Mississippi, natural disasters have caused a need for agricultural credit not readily available from commercial banks, cooperative lending agencies, or other responsible sources.

Pursuant to the authority set forth above, emergency loans will not be made in the above-named county after June 30, 1964, except to applicants who previously received emergency or special livestock loan assistance and who can qualify under established policies and procedures.

Done at Washington, D.C., this 17th day of June 1963.

ORVILLE L. FREEMAN,
Secretary.

[F.R. Doc. 63-6512; Filed, June 19, 1963; 8:57 a.m.]

DEPARTMENT OF COMMERCE

Maritime Administration

LYKES BROS. STEAMSHIP CO., INC.

Notice of Application for Waiver of Permission To Furnish Agency Services

Notice is hereby given that Lykes Bros. Steamship Co., Inc., has filed an application for waiver under the provisions of section 804 of the Merchant Marine Act, 1936, as amended, for permission to furnish agency services, under a sub-agency arrangement with Delta Steamship Lines, Inc., to foreign-flag vessels of the Booth Steamship Company, Ltd., at United States Gulf Coast ports, without solicitation on behalf of the foreign-flag operator.

Any person, firm or corporation having an interest in such application who desires to offer views and comments thereon for consideration by the Maritime Administrator, should submit same in writing, in triplicate, to the Secretary, Maritime Administration, Washington, D.C., by the close of business on July 5, 1963. The Maritime Administrator will consider these views and comments and take such action with respect thereto as may be deemed appropriate.

Dated: June 18, 1963.

By order of the Maritime Administrator.

JAMES S. DAWSON, JR.,
Secretary.

[F.R. Doc. 63-6543; Filed, June 19, 1963; 8:56 a.m.]

LYKES BROS. STEAMSHIP CO., INC.

Notice of Application for Waiver of Permission To Furnish Agency Services

Notice is hereby given that Lykes Bros. Steamship Co., Inc., has filed an application for waiver under the provisions of section 804 of the Merchant Marine Act, 1936, as amended, for permission to furnish agency services, under a sub-agency arrangement with Delta Steamship Lines, Inc., to foreign-flag vessels of Compagnie Maritime Belge, S.A., and its affiliates, Compagnie Maritime Congolaise, S.C.R.L., and/or Deppe Line, at United States Gulf Coast ports,

without solicitation on behalf of the foreign-flag operator.

Any person, firm or corporation having an interest in such application who desires to offer views and comments thereon for consideration by the Maritime Administrator, should submit same in writing, in triplicate, to the Secretary, Maritime Administration, Washington, D.C., by the close of business on July 5, 1963. The Maritime Administrator will consider these views and comments and take such action with respect thereto as may be deemed appropriate.

Dated: June 18, 1963.

By order of the Maritime Administrator.

JAMES S. DAWSON, Jr.,
Secretary.

[F.R. Doc. 63-6544; Filed, June 19, 1963; 8:56 a.m.]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

IMPERIAL CHEMICAL INDUSTRIES LTD.

Notice of Filing of Petition Regarding Food Additives 2,2'Methylene-bis [6-(1 - Methylcyclohexyl) - p - Cresol]

Pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786; 21 U.S.C. 348(b)(5)), notice is given that a petition (FAP 1116) has been filed by Imperial Chemical Industries Limited, Hexagon House, Blackley, Manchester 9, England, proposing the issuance of a regulation to provide for the safe use of 2,2'-methylene - bis [6-(1-methylcyclohexyl) -*p*-cresol] as an antioxidant in polyethylene complying with § 121.2510, provided that the quantity of the antioxidant used does not exceed 0.2 percent by weight of the polyethylene.

Dated: June 13, 1963.

WINTON B. RANKIN,
Assistant Commissioner of Food and Drugs.

[F.R. Doc. 63-6486; Filed, June 19, 1963; 8:50 a.m.]

ATOMIC ENERGY COMMISSION

[Docket No. 27-29]

RADIOLOGICAL SERVICE CO., INC.

Notice of Amendment of Byproduct, Source and Special Nuclear Material License

Please take notice that the Atomic Energy Commission has issued Amendment No. 17 to License No. 31-1672-1 which authorizes the licensee to receive, possess and transport sealed packages containing waste byproduct, source and special nuclear material in any state of the United States except in "Agreement States" as defined in § 150.3(b), 10 CFR 150.

The license amendment provides only for the pick up and transportation of packaged radioactive wastes by the licensee. On October 15, 1962, the State of New York assumed regulatory authority over activities conducted by the licensee in the State of New York. The storage and disposal of radioactive wastes is accomplished under New York regulatory authority. The license amendment does not involve consideration of safety factors different from those previously evaluated and provides only for the continuation of previously authorized activities.

The Commission has determined pursuant to the provisions of 10 CFR, Parts 2, 30, 40 and 70 that the issuance of the amendment is consistent with applicable provisions of law, regulations, and orders issued by the Commission.

In accordance with the Commission's rules of practice, Title 10, Code of Federal Regulations, Chapter 1, Part 2, a formal hearing will be held on the matter upon receipt or request therefor from the licensee or an intervener within 15 days from the date of publication of this notice in the FEDERAL REGISTER.

The text of the amendment is attached to this notice.

Dated at Germantown, Md., June 10, 1963.

For the Atomic Energy Commission.

R. LOWENSTEIN,
Director, Licensing and Regulation.

[License No. 31-1672-1, Amdt. 17]

In accordance with applications dated March 15, 1963, and April 9, 1963, License No. 31-1672-1 is hereby amended in its entirety to read as follows:

Pursuant to the Atomic Energy Act of 1954, as amended, and Title 10, Code of Federal Regulations, Chapter 1, Parts 30, 40 and 70, and subject to the statements and representations contained in the applications, a license is hereby issued to Radiological Service Company, 811 West Merrick Road, Valley Stream, Long Island, New York, to receive and possess sealed packages containing waste byproduct, source, and special nuclear material at customers' facilities in any state of the United States except in "Agreement States" as defined in § 150.3(b), 10 CFR 150, and to transport the sealed packages to its storage facility in the State of New York.

The license shall be deemed to contain the conditions specified in section 183 of the Atomic Energy Act of 1954, as amended, and is subject to the provisions of 10 CFR 20, "Standards for Protection Against Radiation", all other applicable rules, regulations, orders of the Atomic Energy Commission now or hereafter in effect, and to the following conditions:

1. Byproduct, source, and special nuclear material shall be received by Herman Glasser, Ellery Foley, or employees who meet the criteria for training and experience specified in applications dated March 27, 1962, May 15, 1962, and June 4, 1962.

2. The licensee shall only receive byproduct, source, and special nuclear material which has been previously packaged in containers in compliance with applicable Interstate Commerce Commission regulations or with Condition 3 of this license. The containers shall not be opened by the licensee.

3. The transportation of AEC-licensed material shall be subject to the applicable regulations of the Interstate Commerce Commission, United States Coast Guard, and other agencies of the United States having appropriate jurisdiction, and where such regulations are not applicable shall be in accordance with the following requirements except as specifically provided by the Atomic Energy Commission:

A. *Outside shipping containers.* (1) The containers shall meet any one of the following specifications described in Appendix A below:

a. 15A, 15B, 12B, 6A, 6B, 6C, 17C, 17H, 19A, or 19B for the containment of radioactivity in amounts not in excess of 2.7 curies; except polonium, 2 curies; or

b. Specification 55 for containment of solid cobalt 60, cesium 137, iridium 192, or gold 198 in amounts not in excess of 300 curies.

(2) There shall be no radioactive contamination on any exterior surface of the container in excess of 500 d/m/100 sq. cm. alpha and 0.1 mrep/hr beta-gamma radiation.

(3) The smallest dimension of the container shall not be less than 4 inches.

(4) The radiation level at any accessible surface of the container shall not exceed 200 mrem/hr.

(5) At one meter from any point on the radioactive source the radiation level shall not exceed 10 mrem/hr.

(6) Containers which contain radioactive material emitting only alpha and/or beta radiation shall contain sufficient shielding to prevent the escape of primary corpuscular radiation to the exterior surface and to reduce the secondary radiation at the surface of the container so that it does not exceed 10 mrem/24 hours at any time during transportation.

B. *Inside containers.* (1) Solid and gaseous radioactive materials shall be packed in suitable inside containers designed to prevent rupture and leakage under conditions incident to transportation.

(2) Liquid radioactive materials must be packed in sealed glass, earthenware, or other suitable containers. The container must be surrounded on all sides by an absorbent material sufficient to absorb the entire liquid contents and be of such nature that its efficiency will not be impaired by chemical reactions with the contents. Where shielding is required the absorbent material must be placed within the shield. If the inside container meets the Specification 2R in Appendix A the absorbent material is not required.

(3) Materials containing radioisotopes of plutonium, americium, polonium or curium or the isotope strontium 90, in quantities in excess of 100 microcuries, must be packed in containers which meet Specification 2R in Appendix A.

C. *Shielding.* Inside containers must be completely surrounded with sufficient shielding to meet the requirements of subparagraphs A(4), A(5), and A(6) of this condition. The shield must be so designed that it will not open or break under normal conditions incident to transportation.

D. *Labeling.* Each outside container label required under § 20.203(f) of 10 CFR 20 shall bear the following information:

(1) Total activity in millicuries, or in the case of source and special nuclear material, the total weight;

(2) Principal radioisotope;

(3) Radiation level at the surface of the container and at one meter from the source; and

(4) The name and address of the licensee.

E. Each vehicle in which licensed material is transported shall be marked or placarded on each side and the rear with lettering at least 3 inches high as follows: "Dangerous—Radioactive Material".

F. *Accidents.* In the event of an accident involving any vehicle transporting licensed material, immediate steps shall be taken to prevent radiation exposure of persons and to control contamination.

G. *Exemptions.* Specific approval must be obtained from the Atomic Energy Commission for modification of, or exemption from,

the requirements of the license condition. Requests for such approval should be directed to the Chief, Isotopes Branch, Division of Licensing and Regulation, Atomic Energy Commission, and should contain sufficient information to support such a request.

4. The licensee shall not store byproduct, source, and special nuclear material in any of the states in which the licensee is authorized to receive and possess such material.

5. Any container received by the licensee shall not contain more than 20 grams of special nuclear material.

6. Except as specifically authorized otherwise in this license, the licensee shall receive, possess, and transport byproduct, source, and special nuclear material in accordance with statements, representations, and procedures contained in applications dated March 27, 1962, May 15, 1962, June 4, 1962, June 29, 1962, March 15, 1963, and April 9, 1963.

The license amendment shall be effective on the date issued and shall expire two years from the last day of the month in which the license is issued.

Date of issuance: June 10, 1963.

For the Atomic Energy Commission.

R. LOWENSTEIN,
Director, Licensing and Regulation.

[F.R. Doc. 63-6463; Filed, June 19, 1963; 8:46 a.m.]

CIVIL AERONAUTICS BOARD

[Docket 13777; Order No. E-19696]

TRAFFIC CONFERENCE 1 AND JOINT CONFERENCE 1-2 OF THE INTERNATIONAL AIR TRANSPORT ASSOCIATION

Specific Commodity Rates

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., on the 17th day of June 1963.

There has been filed with the Board, pursuant to section 412(a) of the Federal Aviation Act of 1958 (the Act) and Part 261 of the Board's Economic Regulations, agreements between various air carriers, foreign air carriers, and other carriers, embodied in the resolutions of Traffic Conference 1 and Joint Conference 1-2 of the International Air Transport Association (IATA) and adopted pursuant to the provisions of Resolution 590 (Commodity Rates Board).

The agreements, adopted pursuant to unprotested notices to the carriers, name additional specific commodity rates as follows:

ITEM 1101—FURS, HIDES, PELTS AND SKINS

Rates: 39 cents per kilogram, minimum weight 200 kilograms, from Barranquilla to Los Angeles

ITEM 9610—LIGHTERS

Rates: 80 cents per kilogram, minimum weight 500 kilograms, from Vienna to New York

ITEM 8280—PHONOGRAPH RECORDS AND RECORDING TAPE, AND PARTS THEREOF

Rates: 209 cents per kilogram, minimum weight 45 kilograms, from Abadan to New York

Accordingly, it is ordered:

That Agreement C.A.B. 16947, R-28, and Agreement C.A.B. 17006, R-6 and R-7, are approved, provided that such approval shall not constitute approval of the specific commodity descriptions contained therein for purposes of tariff publication.

Any air carrier party to the agreement, or any interested person, may, within 15 days from the date of service of this order, submit statements in writing containing reasons deemed appropriate, together with supporting data, in support of or in opposition to the Board's action herein. An original and nineteen copies of the statements should be filed with the Board's Docket Section. The Board may, upon consideration of any such statements filed, modify or rescind its action herein by subsequent order.

This order will be published in the FEDERAL REGISTER.

By the Civil Aeronautics Board:

[SEAL] HAROLD R. SANDERSON,
Secretary.

[F.R. Doc. 63-6493; Filed, June 19, 1963; 8:52 a.m.]

[Docket 13777; Order No. E-19697]

CONFERENCE 1-2-3 OF THE INTERNATIONAL AIR TRANSPORT ASSOCIATION

Specific Commodity Rates

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., on the 17th day of June 1963.

There has been filed with the Board, pursuant to section 412(a) of the Federal Aviation Act of 1958 (the Act) and Part 261 of the Board's Economic Regulations, an agreement between various air carriers, foreign air carriers, and other carriers embodied in the resolutions of Joint Conferences 1-2-3 of the International Air Transport Association (IATA), and adopted pursuant to the provisions of Resolution 590a—Specific Commodity Rates.

The agreement, adopted pursuant to unprotested notices to the carriers, names an additional specific commodity rate as follows:

Item 2203—Clothing and Footwear, Outerwear, Undergarments; and Parts Thereof; N.E.S., Excluding Umbrellas, Billfolds, Purses, Carrying Cases, Handbags, Costume Jewelry, Jewelry Canes, Watches and Clocks

Rate: 225 cents per kilogram, minimum weight 100 kilograms, from Calcutta to New York.

The Board, acting pursuant to sections 102, 204(a) and 412 of the Act, does not find the above-described agreement to be adverse to the public interest or in violation of the Act, provided that approval thereof is conditioned as hereinafter ordered:

Accordingly, it is ordered:

That Agreement C.A.B. 17022, R-5, is approved, provided that such approval shall not constitute approval of the specific commodity description contained therein for purposes of tariff publication.

Any air carrier party to the agreement, or any interested person may, within 15 days from the date of service of this order, submit statements in writing containing reasons deemed appropriate, together with supporting data, in support of or in opposition to the Board's action herein. An original and 19 copies of the statements should be filed with the Board's Docket Section. The Board may, upon consideration of any such statements filed, modify or rescind its action herein by subsequent order.

This order will be published in the FEDERAL REGISTER.

By the Civil Aeronautics Board:

[SEAL] HAROLD R. SANDERSON,
Secretary.

[F.R. Doc. 63-6494; Filed, June 19, 1963; 8:53 a.m.]

FEDERAL COMMUNICATIONS COMMISSION

[Docket No. 15105; FCC 63-552]

CENTRAL BROADCASTING CO. (WCGC)

Order Designating Application for Hearing on Stated Issues

In re application of Central Broadcasting Company (WCGC), Belmont, North Carolina, Has: 1270 kc, 500 w, 1 kw-LS, DA-N, U, Requests: 1270 kc, 500 w, 5 kw-LS, DA-N, U, Class III, Docket No. 15105, File No. BP-15138; for construction permit.

At a session of the Federal Communications Commission held at its offices in Washington, D.C., on the 12th day of June 1963;

The Commission having under consideration the above-captioned and described application;

It appearing, that, except as indicated by the issues specified below, the applicant is legally, technically, financially, and otherwise qualified to construct and operate as proposed; and

It further appearing, that the following matters are to be considered in connection with the aforementioned issues specified below:

1. The proposal would cause objectionable interference to the existing operations of Stations WHEO, Stuart, Virginia and WSAT, Salisbury, North Carolina.

2. (*a*) The applicant, Central Broadcasting Company, owns 51 percent of the stock of Burke County Broadcasting Company, licensee of Station WSVM, Valdese, North Carolina and a like amount of the stock of Concord-Kannapolis Broadcasting Company, licensee of Station WEGO, Concord, North Carolina. Concord-Kannapolis, in turn, holds 32 percent of the stock of the licensee of Station WPCC, Clinton, South Carolina and 51 percent of the licensee of WZKY, Albemarle, North Carolina. The above stock is voted by Robert R. Hilker, president and 26 percent stockholder of the applicant.

(*b*) Belmont (the proposal) and Concord, North Carolina, location of Station WEGO, are approximately 28 miles

apart. At present, there exists an overlap of their respective normally protected service areas (0.5 mv/m contours). The overlap would be substantially increased in the event of a grant of the subject application.

Due to the proximity of Belmont and Concord, North Carolina, it will be necessary to determine in the hearing ordered below whether a grant of the application would be in contravention of § 3.35(a) of the Commission's rules. Stations WSVM, WZKY and WPCC are located approximately 44, 50, and 72 miles, respectively, from Belmont. Although there would be no overlap between the aforementioned stations and the instant proposal, a substantial question exists regarding the geographical concentration of the broadcast interests of the applicant within a radius of 72 miles of Belmont, North Carolina. Accordingly, in considering the proposal and § 3.35 of the rules, it appears appropriate to consider the size, extent and location of the areas served and to be served, the extent of the overlap involved; the number of persons residing within the overlap area; the classes of stations involved; the extent of other competitive service to the areas in question; the extent to which the stations will rely on the same revenue and program sources; the nature of the programming that the stations will present with particular reference to the needs of the communities they are designated to serve; the advertising practices of the stations; the source of program material and talent for each station; and such other facts as will tend to demonstrate that the overlap and/or concentration of control involved will or will not be in contravention of § 3.35 of the Commission's rules.

It further appearing, that, in view of the foregoing, the Commission is unable to make the statutory finding that a grant of the subject application would serve the public interest, convenience, and necessity, and is of the opinion that the application must be designated for hearing on the issues set forth below:

It is ordered, That, pursuant to section 309(e) of the Communications Act of 1934, as amended, the application is designated for hearing, at a time and place to be specified in a subsequent Order, upon the following issues:

1. To determine the areas and populations which may be expected to gain or lose primary service from the proposed operation of Station WCGC and the availability of other primary service to such areas and populations.

2. To determine whether the proposal of Central Broadcasting Company would cause objectionable interference to Stations WHEO, Stuart, Virginia, and WSAT, Salisbury, North Carolina, or any other existing standard broadcast stations, and, if so, the nature and extent thereof, the areas and populations affected thereby, and the availability of other primary service to such areas and populations.

3. To determine whether a grant of the proposal of Central Broadcasting Company would be in contravention of the provisions of §3.35(a) of the Commission rules with respect to multiple ownership of standard broadcast stations.

4. To determine whether a grant of the proposal of Central Broadcasting Company would be in contravention of § 3.35(b) of the Commission rules with respect to concentration of control.

5. To determine, in the light of the evidence adduced pursuant to the foregoing issues, whether a grant of the application would serve the public interest, convenience and necessity.

It is further ordered, That, Patrick Henry Broadcasting Corporation and Mid-Carolina Broadcasting Company, licensees of Stations WHEO and WSAT, respectively, are made parties to the proceeding.

It is further ordered, That, in the event of a grant of the instant application, the construction permit shall contain the following conditions:

Pending a final decision in Docket No. 14419 with respect to presunrise operation with daytime facilities, the present provisions of § 3.87 of the Commission rules are not extended to this authorization, and such operation is precluded.

Permittee shall submit new common point impedance measurements and sufficient field intensity measurement data to show clearly that the installation and adjustment of any new components required, as a result of daytime power increase, has not adversely affected the operation of the nighttime directional array.

Permittee shall submit sufficient field intensity measurement data to establish that the radiation has been reduced to essentially 175 mv/m/kw as proposed.

Permittee shall submit with the application for license antenna resistance measurements made in accordance with § 3.54 of the Commission rules.

It is further ordered, That, to avail themselves of the opportunity to be heard, the applicant and parties respondent herein, pursuant to § 1.140 of the Commission rules, in person or by attorney, shall, within 20 days of the mailing of this Order, file with the Commission in triplicate, a written appearance stating an intention to appear on the date fixed for the hearing and present evidence on the issues specified in this Order.

It is further ordered, That the applicant herein shall, pursuant to section 311(a)(2) of the Communications Act of 1934, as amended, and § 1.362(b) of the Commission's rules, give notice of the hearing, within the time and in the manner prescribed in such Rule, and shall advise the Commission of the publication of such notice as required by § 1.362(h) of the rules.

Released: June 17, 1963.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

[F.R. Doc. 63-6497; Filed, June 19, 1963; 8:53 a.m.]

[Docket Nos. 15106, 15107; FCC 63-553]

COMMUNITY BROADCASTING CO., INC., (WHPB) AND CLEVELAND COUNTY BROADCASTING CO., INC., (WADA)

Order Designating Applications for Consolidated Hearing on Stated Issues

In re applications of Community Broadcasting Company, Inc. (WHPB) Belton, South Carolina, Has: 1390 kc, 500 w, Day, Class III, Requests: 1390 kc, 1 kw, Day, Class III, Docket No. 15106, File No. BP-14476; Cleveland County Broadcasting Co., Inc. (WADA), Shelby, North Carolina, Has: 1390 kc, 500 w, Day, Class III, Requests: 1390 kc, 500 w, 1 kw-LS, DA-N, U, Class III, Docket No. 15107, File No. BP-15269; for construction permits.

At as session of the Federal Communications Commission held at its offices in Washington, D.C., on the 12th day of June 1963;

The Commission having under consideration the above-captioned and described applications;

It appearing, that, except as indicated by the issues specified below, each of the applicants is legally, technically, financially, and otherwise qualified to construct and operate as proposed; and

It further appearing, that the following matters are to be considered in connection with the aforementioned issues specified below:

1. Each proposal would cause interference to the existing and proposed operations of the other. Because of conflicting data submitted by applicants, it has yet to be determined whether the proposal of WHPB would comply with the provisions of § 3.28(d)(3) of the Commission's rules.

2. A study submitted by Cleveland County Broadcasting Co., Inc., purports to show that their proposal would not result in nighttime interference to Station WCSC, Charleston, South Carolina, but studies by the Commission indicate that the nighttime RSS service area of Station WCSC would receive interference from the proposal.

3. The proposal of Community Broadcasting Company, Inc. would cause slight objectionable interference to Station WSGC, Elberton, Georgia.

It further appearing, that, in view of the foregoing, the Commission is unable to make the statutory finding that a grant of the subject applications would serve the public interest, convenience, and necessity, and is of the opinion that the applications must be designated for hearing in a consolidated proceeding on the issues set forth below:

It is ordered, That, pursuant to section 309(e) of the Communications Act of 1934, as amended, the applications are designated for hearing in a consolidated proceeding, at a time and place to be specified in a subsequent Order, upon the following issues:

1. To determine the areas and populations which may be expected to gain or

lose primary service from the proposed operations of Stations WHPB and WADA, respectively, and the availability of other primary service to such areas and populations.

2. To determine the nature and extent of the interference, if any, that each of the proposals would cause to and receive from each other and the interference that each of the proposals would receive from all other existing standard broadcast stations, the areas and populations affected thereby, and the availability of other primary service to the areas and populations affected by interference from either of the proposals.

3. To determine whether interference received from all sources would affect more than ten percent of the population within the normally protected primary service area of the proposed operation of Station WHPB, in contravention of § 3.28(d) (3) of the Commission rules, and, if so, whether circumstances exist which would warrant a waiver of said section.

4. To determine whether the proposal of WHPB would cause objectionable interference to Stations WADA, Shelby, North Carolina, and WSGC, Elberton, Georgia, respectively, or any other existing standard broadcast stations, and, if so, the nature and extent thereof, the areas and populations affected thereby, and the availability of other primary service to such areas and populations.

5. To determine whether the proposal of WADA would cause objectionable interference to Station WHPB, Belton, South Carolina, or any other existing standard broadcast stations, and, if so, the nature and extent thereof, the areas and populations affected thereby, and the availability of other primary service to such areas and populations.

6. To determine whether the proposal of WADA would cause objectionable nighttime interference to Station WCSC, Charleston, South Carolina, or any other existing standard broadcast stations, and, if so, the nature and extent thereof, the areas and populations affected thereby, and the availability of other primary service to such areas and populations.

7. To determine, in the light of section 307(b) of the Communications Act of 1934, as amended, which of the proposals would better provide a fair, efficient and equitable distribution of radio service.

8. To determine, in the light of the evidence adduced pursuant to the foregoing issues which, if either, of the applications should be granted.

It is further ordered, That both of the applicants herein are made parties to the proceeding with respect to their existing operations.

It is further ordered, That WCSC, Inc. and Elberton Broadcasting Company, licensees of Stations WCSC and WSGC, respectively, are made parties to the proceeding.

It is further ordered, That, in the event of a grant of either of the applications herein, the construction permits shall contain the following condition: Pending a final decision in Docket No. 14419 with respect to presunrise operation with daytime facilities, the present provisions of § 3.87 of the Commission rules are not extended to this authorization, and such operation is precluded.

It is further ordered, That, in the event of a grant of the application of Community Broadcasting Company, Inc., the construction permit shall contain the following condition: Permittee shall submit with the application for license antenna resistance measurements made in accordance with § 3.54 of the Commission's rules.

It is further ordered, That, to avail themselves of the opportunity to be heard, the applicants and parties respondent herein, pursuant to § 1.140 of the Commission rules, in person or by attorney, shall, within 20 days of the mailing of this Order, file with the Commission in triplicate, a written appearance stating an intention to appear on the date fixed for the hearing and present evidence on the issue specified in this Order.

It is further ordered, That the applicants herein shall, pursuant to section 311(a)(2) of the Communications Act of 1934, as amended, and § 1.362(b) of the Commission's rules, give notice of the hearing, either individually or, if feasible, jointly, within the time and in the manner prescribed in such rule, and shall advise the Commission of the publication of such notice as required by § 1.362 (h) of the rules.

It is further ordered, That, the issues in the above-captioned proceeding may be enlarged by the Examiner, on his own motion or on petition properly filed by a party to the proceeding, and upon sufficient allegations of fact in support thereof, by the addition of the following issue: To determine whether the funds available to the applicant will give reasonable assurance that the proposals set forth in the application will be effectuated.

Released: June 17, 1963.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

[F.R. Doc. 63-6498; Filed, June 19, 1963; 8:53 a.m.]

[Docket No. 15064; FCC 63M-677]

EASTSIDE BROADCASTING CO.

Order Continuing Hearing

In re application of L. N. Ostrander & G. A. Wilson, d/b as Eastside Broadcasting Company, Phoenix, Arizona, Docket No. 15064, File No. BP-15022; for construction permit.

Pursuant to agreement of counsel arrived at during the prehearing conference in the above-styled proceeding held on this date: *It is ordered,* This 10th day of June 1963, that the hearing presently scheduled to commence on July 15, 1963, is continued to October 2, 1963, at 10 a.m., in Washington, D.C.

Released: June 11, 1963.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

[F.R. Doc. 63-6499; Filed, June 19, 1963; 8:53 a.m.]

[Docket No. 15104; FCC 63-551]

HAMPDEN-HAMPSHIRE CORP. (WHYN)

Memorandum Opinion and Order Designating Application for Hearing on Stated Issues

In re application of The Hampden-Hampshire Corporation (WHYN), Springfield, Massachusetts, Has: 560kc, 1kw, DA-1, U, Class III, Requests: 560kc, 1kw, 5kw-LS, DA-2, U, Class III, Docket No. 15104, File No. BP-15066; for construction permit.

1. The Commission has before it the above-captioned and described application, and a "Petition to Designate Application for Hearing" filed October 5, 1961 by Guy Gannett Broadcasting Services, licensee of Station WGAN, Portland, Maine.

2. The petitioner requests that the application be designated for hearing on the ground that the proposal would increase the interference which Station WGAN presently receives from the existing operation of Station WHYN. An interference study, based on data submitted by the applicant, indicates that the proposal would raise that portion of the population within the normally protected primary service area of Station WGAN affected by the interference from 9.0 percent to 9.3 percent.

3. The applicant's data also indicate that slight objectionable interference would be caused to the existing operations of Stations WXTR and WTAG, located at Pawtucket, Rhode Island and Worcester, Massachusetts, respectively.

4. In view of the foregoing, except as indicated by the issues specified below, the applicant is legally, technically, financially and otherwise qualified to construct and operate as proposed. However, the Commission is of the opinion that substantial and material questions of fact are presented and that the application should, therefore, be designated for hearing with the licensees of the aforementioned stations being made parties thereto on the issues set forth below.

Accordingly, it is ordered, This 12th day of June 1963, That, pursuant to section 309(e) of the Communications Act of 1934, as amended, the application is designated for hearing, at a time and place to be specified in a subsequent Order, upon the following issues:

1. To determine the areas and populations which may be expected to gain or lose primary service from the proposed operation of Station WHYN and the availability of other primary service to such areas and populations.

2. To determine whether the proposal of Station WHYN would cause objectionable interference to Stations WGAN, Portland, Maine, WTAG, Worcester, Massachusetts, and WXTR, Pawtucket, Rhode Island, or any other existing standard broadcast stations, and, if so, the nature and extent thereof, the areas and populations affected thereby, and the availability of other primary service to such areas and populations.

3. To determine, in the light of the evidence adduced pursuant to the foregoing issues, whether a grant of the ap-

plication would serve the public interest, convenience and necessity.

It is further ordered, That the "Petition To Designate Application For Hearing", filed on October 5, 1961, by Guy Gannett Broadcasting Services, is hereby granted.

It is further ordered, That Guy Gannett Broadcasting Services, WTAG, Inc., and Roger Williams Broadcasting Company, Inc., licensees of Stations WGAN, WTAG and WXTR, respectively, are made parties to the proceeding.

It is further ordered, That, in the event of a grant of the instant proposal, the construction permit shall contain the following conditions:

Before program tests are authorized, permittee shall submit sufficient field intensity measurement data to establish that the change in components for increased daytime power has not adversely affected the nighttime radiation pattern.

Pending a final decision in Docket No. 14419 with respect to pre-sunrise operation with daytime facilities, the present provisions of § 3.87 of the Commission rules are not extended to this authorization, and such operation is precluded.

Permittee shall submit with the application for license equipment proof-of-performance measurements made in accordance with the provisions of § 3.47 of the Commission rules.

It is further ordered, That, to avail themselves of the opportunity to be heard, the applicant and parties respondent herein, pursuant to § 1.140 of the Commission rules, in person or by attorney, shall, within 20 days of the mailing of this order, file with the Commission in triplicate, a written appearance stating an intention to appear on the date fixed for the hearing and present evidence on the issues specified in this order.

It is further ordered, That the applicant herein shall, pursuant to section 311(a)(2) of the Communications Act of 1934, as amended, and § 1.362(b) of the Commission's rules, give notice of the hearing, within the time and in the manner prescribed in such rule, and shall advise the Commission of the publication of such notice as required by § 1.362(h) of the rules.

Released: June 17, 1963.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

[F.R. Doc. 63-6500; Filed, June 19, 1963; 8:54 a.m.]

[Docket No. 15103]

GEORGE H. HARPER, SR.

Order To Show Cause

In the matter of George H. Harper, Sr., Los Angeles, California, Docket No. 15103; order to show cause why there should not be revoked the license for Citizens Radio Station 11W6313.

The Commission, by the Chief, Safety and Special Radio Services Bureau, under delegated authority, having under consideration certain alleged violations in the operation of Citizens Radio Station 11W6313;

It appearing, that, on or about November 11, 1962, licensee willfully transmitted, by means of the captioned radio station, communications containing obscene, indecent, or profane language, in violation of Title 18, United States Code, section 1464; and

It further appearing, that, on or about November 11, 1962, licensee willfully transmitted, by means of the captioned radio station, communications to units of other Citizens radio stations which were not necessary for the exchange of substantive messages related to the business or personal affairs of the individuals concerned, in violation of § 19.61 (a) of the Commission's rules;

It is ordered, This 14th day of June 1963, pursuant to section 312(a)(4) and (6) and (c) of the Communications Act of 1934, as amended, and § 0.291(b)(8) of the Commission's rules, that the licensee show cause why the license for the captioned radio station should not be revoked and appear and give evidence with respect thereto at a hearing to be held at a time and place to be specified by subsequent order:

And it is further ordered, That the Secretary send a copy of this order by Certified Mail—Return Receipt Requested to the licensee at his last known address of 755 East 97 Street, Los Angeles, Calif.

Released: June 17, 1963.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

[F.R. Doc. 63-6501; Filed, June 19, 1963; 8:54 a.m.]

[Docket No. 15126]

J & S INC.

Order To Show Cause

In the matter of J & S INCORPORATED, New Orleans, Louisiana, Docket No. 15126; order to show cause why there should not be revoked the license for Radio Station WC-2819 aboard the vessel "Harry Dyer."

The Commission, by the Chief, Safety and Special Radio Services Bureau, under delegated authority, having under consideration the matter of certain alleged violations of the Commission's rules in connection with the operation of the above-captioned station;

It appearing, that, pursuant to section 308(b) of the Communications Act of 1934, as amended, the above-named licensee was requested to furnish information concerning the subject radio station in communications dated February 11, March 22, and May 22, 1963, and sent to the licensee's address of record, but no response thereto has been received; and

It further appearing, that, in view of the foregoing, the licensee has repeatedly violated section 308(b) of the Communications Act of 1934, as amended, and § 1.76 of the Commission's rules:

It is ordered, This 13th day of June 1963, pursuant to section 312(a)(4) and (c) of the Communications Act of 1934, as amended, and § 0.291(b)(8) of Part 0 of the Commission's rules, that said licensee show cause why the license for the above-captioned radio station should not be revoked, and appear and give evidence in respect thereto at a hearing to be held at a time and place to be specified by subsequent order:

And it is further ordered, That the Secretary send a copy of this order by Certified Mail—Return Receipt Requested to the said licensee at the address of record at 1460 Oil and Gas Building, 1100 Tulane Avenue, New Orleans, La.

Released: June 17, 1963.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

[F.R. Doc. 63-6502; Filed, June 19, 1963; 8:54 a.m.]

[Docket No. 15108—15110; FCC 63-554]

PIEDMONT BROADCASTING CO. ET AL.

Order Designating Applications for Consolidated Hearing on Stated Issues

In re applications of William H. Kirby and John B. Burns d/b as Piedmont Broadcasting Co., Travelers Rest, South Carolina, Requests: 1580 kc, 500 w, Day, Class II, Docket No. 15108, File No. BP-14527; James C. Liles tr/as Hentron Broadcasting Company, Hendersonville, North Carolina, Requests: 1580 kc, 1 kw, Day, Class II, Docket No. 15109, File No. BP-15026; The Mountainaire Corporation, Hendersonville, North Carolina, Requests: 1600 kc, 1 kw, DA-D, Class III, Docket No. 15110, File No. BP-15274; for construction permits.

At a session of the Federal Communications Commission held at its offices in Washington, D.C., on the 12th day of June 1963;

The Commission having under consideration the above-captioned and described applications;

It appearing, that, except as indicated by the issues specified below, each of the applicants is legally, technically, financially, and otherwise qualified to construct and operate as proposed; and

It further appearing, that the following matters are to be considered in connection with the aforementioned issues specified below:

1. The proposal of Hentron Broadcasting Company would cause objectionable interference to the existing operation of Station WKJK, Granite Falls, North Carolina.

2. The proposal of Hentron Broadcasting Company is mutually exclusive with the proposal of Mountainaire Corporation and involves mutually destructive interference with the proposal of Piedmont Broadcasting Co.

It further appearing, that, in view of the foregoing, the Commission is unable to make the statutory finding that a grant of the subject applications would serve the public interest, convenience, and necessity, and is of the opinion that

the applications must be designated for hearing in a consolidated proceeding on the issues set forth below:

It is ordered, That, pursuant to section 309(e) of the Communications Act of 1934, as amended, the applications are designated for hearing in a consolidated proceeding, at a time and place to be specified in a subsequent Order, upon the following issues:

1. To determine the areas and populations which would receive primary service from each of the proposals herein and the availability of other primary service to such areas and populations.

2. To determine whether the proposal of Hentron Broadcasting Company would cause objectionable interference to Station WKJK, Granite Falls, North Carolina, or any other existing standard broadcast stations, and, if so, the nature and extent thereof, the areas and populations affected thereby, and the availability of other primary service to such areas and populations.

3. To determine, in the light of section 307(b) of the Communications Act of 1934, as amended, which of the proposals would best provide a fair, efficient and equitable distribution of radio service.

4. To determine, in the event it is concluded that a choice between the applications should not be based solely on considerations relating to section 307(b), which of the operations proposed in the above-captioned applications would better serve the public interest, in light of the evidence adduced pursuant to the foregoing issues and the record made with respect to the significant differences between the applicants as to:

(a) The background and experience of each having a bearing on the applicant's ability to own and operate the proposed standard broadcast station.

(b) The proposals of each of the applicants with respect to the management and operation of the proposed stations.

(c) The programing services proposed in each of the applications.

5. To determine, in the light of the evidence adduced pursuant to the foregoing issues which, if any, of the applications should be granted.

It is further ordered, That James B. Childress, licensee of Station WKJK, Granite Falls, North Carolina, is made a party to the proceeding.

It is further ordered, That, in the event of a grant of the application of Piedmont Broadcasting Co., the construction permit shall contain the following condition: This authorization is subject to compliance by permittee with any applicable procedures of the FAA.

It is further ordered, That, in the event of a grant of the application of The Mountainaire Corporation, the construction permit shall contain the following condition: Pending a final decision in Docket No. 14419 with respect to presunrise operation with daytime facilities, the present provisions of § 3.87 of the Commission rules are not extended to this authorization, and such operation is precluded.

It is further ordered, That, to avail themselves of the opportunity to be heard, the applicants and party respondent herein, pursuant to § 1.140 of the Commission rules, in person or by attorney, shall, within 20 days of the mailing of this Order, file with the Commission in triplicate, a written appearance stating an intention to appear on the date fixed for the hearing and present evidence on the issues specified in this Order.

It is further ordered, That the applicants herein shall, pursuant to section 311(a)(2) of the Communications Act of 1934, as amended, and § 1.362(b) of the Commission's rules, give notice of the hearing, either individually or, if feasible, jointly, within the time and in the manner prescribed in such rule, and shall advise the Commission of the publication of such notice as required by § 1.362(h) of the rules.

It is further ordered, That, the issues in the above-captioned proceeding may be enlarged by the Examiner, on his own motion or on petition properly filed by a party to the proceeding, and upon sufficient allegations of fact in support thereof, by the addition of the following issue: To determine whether the funds available to the applicant will give reasonable assurance that the proposals set forth in the application will be effectuated.

Released: June 17, 1963.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

[F.R. Doc. 63-6503; Filed, June 19, 1963; 8:55 a.m.]

[Docket No. 15127]

GINO TURCHIARO

Order To Show Cause

In the matter of Gino Turchiaro, Bronx, New York, Docket No. 151287; order to show cause why there should not be revoked the license for Radio Station KCI-1496 in the Citizens Radio Service.

The Commission, by the Chief, Safety and Special Radio Services Bureau, under delegated authority, having under consideration the matter of certain alleged violations of the Commission's rules in connection with the operation of the above-captioned station;

It appearing, that, pursuant to § 1.76 of the Commission's rules, written notice of violation of the Commission's rules was served upon the above-named licensee at his address of record as follows: Letter dated March 20, 1963, alleging violation of § 19.61 (a) (f), and (g) of the Commission's rules.

It further appearing, that said licensee did not reply to such communication or to a follow-up letter dated May 29, 1963, also mailed to the licensee at his address of record; and

It further appearing, that, in view of the foregoing, the licensee has repeatedly violated § 1.76 of the Commission's rules:

It is ordered, This 13th day of June 1963, pursuant to section 312 (a)(4) and (c) of the Communications Act of 1934, as amended, and § 0.291(b)(8) of Part 0 of the Commission's rules, that the said licensee show cause why the license for the above-captioned radio station should not be revoked, and appear and give evidence in respect thereto at a hearing to be held at a time and place to be specified by subsequent order:

And it is further ordered, That the Secretary send a copy of this order by Certified Mail—Return Receipt Requested to the said licensee at his last known address of 460 East 184th Street, Bronx, N.Y.

Released: June 17, 1963.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

[F.R. Doc. 63-6504; Filed, June 19, 1963; 8:55 a.m.]

FEDERAL MARITIME COMMISSION

[Fact Finding Investigation No. 4]

TERMINAL PRACTICES AT NORTH ATLANTIC PORTS (HAMPTON ROADS, VA. TO SEARSPORT, MAINE)

Notice of Hearing

JUNE 17, 1963.

A hearing in this proceeding will be held by the undersigned beginning at 10:00 a.m., August 1, 1963, at hearing room 705, 45 Broadway, New York, New York.

The hearing will be public.

JAMES A. KEMPKER,
Investigative Officer.

[F.R. Doc. 63-6495; Filed, June 19, 1963; 8:53 a.m.]

PRESIDENT'S CABINET TEXTILE ADVISORY COMMITTEE

CERTAIN COTTON TEXTILES, MANUFACTURE OF REPUBLIC OF CHINA

Modification of Outstanding Levels of Restraint on Import

JUNE 7, 1963.

On December 20, 1962, the Chairman of the President's Cabinet Textile Advisory Committee directed the Commissioner of Customs to prohibit beyond listed levels entry into the United States and withdrawal from warehouse for consumption in the United States of cotton textiles and cotton textile products in eleven categories, including Categories 9, 31, 50, and 51, produced or manufactured in the Republic of China. This directive was published in accordance with the request of the Chairman in the FEDERAL REGISTER of December 28, 1962 (27 F.R. 12850).

A schedule accompanied that directive setting forth the maximum levels of the respective categories which might be entered into the United States during stated intervals for consumption.

On March 15, 1963, the Commissioner of Customs was directed to increase the amounts of Category 51 by stated

amounts. This directive was published in the FEDERAL REGISTER of April 4, 1963 (28 F.R. 3285).

The United States Government has negotiated with the Republic of China a modification of the levels of restraint of Categories 9, 31, and 50, announced on December 20, 1962 (27 F.R. 12850) providing for a decrease in the allowable entries of these three categories as an adjustment for the increase allowed in Category 51. To the extent that importers have, on the basis of the levels announced on December 20, 1962, entered into enforceable contracts with suppliers in the Republic of China for goods in these three categories and the goods so contracted for may not be entered into this country becauses of such decreased levels, such importers are invited to submit the facts concerning the particular transactions to the Chairman of the Interagency Textile Administrative Committee, U.S. Department of Commerce, Washington 25, D.C., for consideration by that Committee.

LUTHER H. HODGES,
Secretary of Commerce, and Chairman, President's Cabinet Textile Advisory Committee.

[F.R. Doc. 63-6482; Filed, June 19, 1963; 8:50 a.m.]

SECURITIES AND EXCHANGE COMMISSION

[File No. 1-3421]

CONTINENTAL VENDING MACHINE CORP.

Order Summarily Suspending Trading

JUNE 14, 1963.

The common stock, 10 cents par value, of Continental Vending Machine Corp., being listed and registered on the American Stock Exchange and having unlisted trading privileges on the Philadelphia-Baltimore-Washington Stock Exchange, and the 6 percent convertible subordinated debentures due September 1, 1976 being listed and registered on the American Stock Exchange; and

The Commission being of the opinion that the public interest requires the summary suspension of trading in such securities on such Exchanges and that such action is necessary and appropriate for the protection of investors; and

The Commission being of the opinion further that such suspension is necessary in order to prevent fraudulent, deceptive or manipulative acts or practices, with the result that it will be unlawful under section 15(c)(2) of the Securities Exchange Act of 1934 and the Commission's Rule 15c2-2 thereunder for any broker or dealer to make use of the mails or of any means or instrumentality of interstate commerce to effect any transaction in, or to induce or attempt to induce the purchase or sale of any such security, otherwise than on a national securities exchange;

It is ordered, Pursuant to section 19(a)(4) of the Securities Exchange Act of 1934, that trading in such securities on the American Stock Exchange and the Philadelphia-Baltimore-Washington Stock Exchange be summarily suspended in order to prevent fraudulent, deceptive or manipulative acts or practices, this order to be effective for the period June 16, 1963, through June 25, 1963, both dates inclusive.

By the Commission.

[SEAL] ORVAL L. DUBOIS,
Secretary.

[F.R. Doc. 63-6492; Filed, June 19, 1963; 8:52 a.m.]

SMALL BUSINESS ADMINISTRATION

[Delegation of Authority No. 30-IV-42]

MANAGER OF DISASTER FIELD OFFICE, NORTON, VA.

Delegation of Authority Regarding Financial Assistance Functions

Notice is hereby given that Delegation of Authority No. 30-IV-42 (28 F.R. 3368), is hereby rescinded in its entirety.

Effective date: June 10, 1963.

CLARENCE P. MOORE,
Regional Director, Region IV, Richmond, Virginia.

[F.R. Doc. 63-6484; Filed, June 19, 1963; 8:50 a.m.]

[Delegation of Authority, No. 30-IV-43]

MANAGER OF DISASTER FIELD OFFICE, LOGAN, W. VA.

Delegation of Authority Regarding Financial Assistance Functions

Notice is hereby given that Delegation of Authority No. 30-IV-43 (28 F.R. 3368), is hereby rescinded in its entirety.

Effective date: June 10, 1963.

CLARENCE P. MOORE,
Regional Director, Region IV, Richmond, Virginia.

[F.R. Doc. 63-6485; Filed, June 19, 1963; 8:50 a.m.]

[Declaration of Disaster Area 433]

OHIO

Declaration of Disaster Area

Whereas, it has been reported that during the month of June 1963, because of the effects of certain disasters, damage resulted to residences and business property located in Guernsey County in the State of Ohio;

Whereas, the Small Business Administration has investigated and has received other reports of investigations of conditions in the area affected;

Whereas, after reading and evaluating reports of such conditions, I find that the conditions in such area constitute a catastrophe within the purview of the Small Business Act, as amended.

Now, therefore, as Acting Deputy Administrator of the Small Business Administration, I hereby determine that:

1. Applications for disaster loans under the provisions of section 7(b)(1) of the Small Business Act, as amended, may be received and considered by the Offices below indicated from persons or firms whose property, situated in the aforesaid County and areas adjacent thereto, suffered damage or destruction resulting from floods and accompanying conditions occurring on or about June 7, 1963.

OFFICES

Small Business Administration Regional Office,
1370 Ontario Street,
Cleveland 13, Ohio.

Small Business Administration Branch Office,
Beacon Building,
50 West Gay Street,
Columbus, Ohio.

2. Applications for disaster loans under the authority of this Declaration will not be accepted subsequent to December 31, 1963.

Dated: June 10, 1963.

LOGAN B. HENDRICKS,
Acting Deputy Administrator.

[F.R. Doc. 63-6476; Filed, June 19, 1963; 8:48 a.m.]

INTERSTATE COMMERCE COMMISSION

FOURTH SECTION APPLICATION FOR RELIEF

JUNE 17, 1963.

Protests to the granting of an application must be prepared in accordance with Rule 1.40 of the general rules of practice (49 CFR 1.40) and filed within 15 days from the date of publication of this notice in the FEDERAL REGISTER.

LONG-AND-SHORT HAUL

FSA No. 38377: *Joint motor-rail rates—Niagara Frontier.* Filed by Niagara Frontier Tariff Bureau, Inc., agent (No. 3), for interested carriers. Rates on property moving on class and commodity rates over joint routes of applicant rail and motor carriers, between points in central and middlewest territories, on the one hand, and points in provinces of Ontario and Quebec, Canada, on the other.

Grounds for relief: Motortruck competition.

Tariff: Supplement 11 to Niagara Frontier Tariff Bureau, Inc., agent, tariff MF-I.C.C. 53.

By the Commission.

[SEAL] HAROLD D. McCOY,
Secretary.

[F.R. Doc. 63-6480; Filed, June 19, 1963; 8:49 a.m.]

[Notice 821]

MOTOR CARRIER TRANSFER PROCEEDINGS

JUNE 17, 1963.

Synopses of orders entered pursuant to section 212(b) of the Interstate Commerce Act, and rules and regulations prescribed thereunder (49 CFR Part 179), appear below:

As provided in the Commission's special rules of practice any interested person may file a petition seeking reconsideration of the following numbered proceedings within 20 days from the date of publication of this notice. Pursuant to section 17(8) of the Interstate Commerce Act, the filing of such a petition will postpone the effective date of the order in that proceeding pending its disposition. The matters relied upon by petitioners must be specified in their petitions with particularity.

No. MC–FC 65720. By order of June 13, 1963, the Transfer Board approved the transfer to Walton Drayage & Warehouse Co., Inc., Alameda, Calif., of the operating rights claimed in No. MC 99335 (Sub-No. 2), under the "grandfather clause" of section 206(a)(7)(b), Interstate Commerce Act, by William B. Walton, doing business as Walton Drayage & Warehouse Co., Alameda, Calif., for which a certificate of registration to operate in interstate or foreign commerce is sought, corresponding to a grant of intrastate authority issued transferor by the California Public Utilities Commission in decisions Nos. 50986, 63582 and 64680. Daniel W. Baker, 625 Market Street, San Francisco 5, Calif., attorney for applicants.

No. MC–FC 65997. By order of June 13, 1963, the Transfer Board approved the transfer to S. & S. Auto Freight, Inc., Seattle, Wash., of certificate in No. MC 52530, issued February 4, 1952 to Lloyd D. Heffernan, doing business as S. & S. Auto Freight, Seattle, Wash., and certificate in No. MC 124477 (Sub-No. 1), issued March 8, 1963, to Robert E. Swanson and Lloyd Heffernan, a partnership, doing business as Seattle-Eastside Auto Freight, Seattle, Wash., authorizing the transportation in No. MC 52530 of: General commodities, excluding household goods, commodities in bulk, and other specified commodities, between Seattle and Kirkland, Wash., and general commodities, without exception, between Seattle and Carnation, Wash., and in No. MC 124477 (Sub-No. 1), general commodities, except household goods, commodities in bulk, and other specified commodities, between Seattle, and Bellevue and Factoria, Wash. Carl A. Jonson, 400 Central Building, Seattle 4, Wash., attorney for applicants.

No. MC–FC 66011. By order of June 13, 1963, the Transfer Board approved the transfers to Ophelia Maddy, doing business as Canfield Truck Line, Kansas City, Mo., of a corrected certificate in No. MC 105802 issued September 30, 1949, to Jess B. Maddy, doing business as Canfield Truck Line, Kansas City, Mo., authorizing the transport of general commodities, excluding household goods and commodities in bulk, over a regular route, between Nevada, Mo., and Kansas City, Kans., with service authorized to and from the intermediate points of Arthur, Horton, Rich Hill, Butler, Passaic, Archie, Harrisonville, and Kansas City, Co. Manfred Maier, 1212 Home Savings Building, Kansas City 6, Mo., attorney for applicants.

No. MC–FC 66017. By order of June 13, 1963, the Transfer Board approved the transfer to Bianco Bros., Inc., New York, N.Y., of certificate in No. MC 23802 (Sub-No. 2), issued August 15, 1960, to Aniello Bianco, Joseph Bianco, Anthony Bianco, Sol Bianco, and Michael Bianco, a partnership, doing business as Bianco Bros., New York, N.Y., authorizing the transportation, over irregular routes, of: Fresh and frozen meats, from New York, N.Y., to South Kearny, Hawthorne, and Newark, N.J. William D. Traub, 10 East 40th Street, New York 16, N.Y., representative for applicants.

No. MC–FC 65830. By order of June 14, 1963, the Transfer Board approved the substitution of Poteet Transfer Co., Inc., Morrilton, Ark., in lieu of J. D. Poteet and V. D. Poteet, a partnership, doing business as Poteet Transfer Co., Morrilton, Ark., as applicant in No. MC 28892 (Sub-No. 3) (BOR 99) for a certificate of registration to operate in interstate or foreign commerce authorizing operations under the former second proviso of section 206(a)(1) of the Act supported by Arkansas Certificate No. B–219 authorizing the transportation of general commodities, over regular routes, from Morrilton, Arkansas, to Little Rock, Arkansas, and over irregular routes, household goods, cotton, used farm equipment, and farm products, from and to specified points in Arkansas. Louis Tarlowski, 914 Pyramid Life Building, Little Rock, Ark., representative for applicants.

No. MC–FC 65877. By order of June 14, 1963, the Transfer Board approved the transfer to Clark Bros. Transfer, Inc., Norfolk, Nebr., of the operating rights set forth in certificate in No. MC 106195 (Sub-No. 2) issued April 4, 1957, to Fred L. Clark and Walter F. Clark, doing business as Clark Brothers Transfer, Norfolk, Nebr., authorizing the transportation, over regular routes, of general commodities, excluding household goods, commodities in bulk, and other specified commodities, between specified points in Nebraska and Iowa. Donald E. Leonard, Third Floor, N.S.E.A. Building, 14th and J Streets, Lincoln, Nebr., attorney for applicants.

No. MC–FC 65991. By order of June 14, 1963, the Transfer Board approved the transfer to L.P. Transportation, Inc., Chester, N.Y., of certificate in No. MC 109918, issued August 11, 1954, to Ampro-Pane Transport, Inc., Chester, N.Y., authorizing the transportation of liquefied propane gas, in bulk, in tank vehicles, from Newark, N.J., to all points in Maine, New Hampshire, Vermont, Massachusetts, Connecticut, Rhode Island, New York, New Jersey, Pennsylvania, Maryland, Delaware, and the District of Columbia. Edward M. Alfano, Werner & Alfano, 2 West 45th Street, New York, N.Y., attorney for applicants.

[SEAL] HAROLD D. MCCOY,
Secretary.

[F.R. Doc. 63-6481; Filed, June 19, 1963; 8:50 a.m.]

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PART II

FEDERAL REGISTER

VOLUME 28 NUMBER 120

Washington, Thursday, June 20, 1963

Rules and Regulations

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER A—GENERAL

PART 1—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Drugs; Statement of Ingredients; Prescription-Drug Advertisements

The Commissioner of Food and Drugs has considered the views and objections received in response to the notice of proposed rulemaking published in the FEDERAL REGISTER of February 14, 1963 (28 F.R. 1448). Some of the suggested changes have been adopted, in whole or in part, as will be seen from the following order, issued pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502 (e), (n), 701(a); 52 Stat. 1050, 1051, as amended, 76 Stat. 790, 791, 792, 1055; 21 U.S.C. 352 (e), (n), 371(a)) and under the authority delegated to the Commissioner by the Secretary of Health, Education, and Welfare (25 F.R. 8625).

Part 1 is amended by revoking § 1.105 and by adding thereto new §§ 1.104 and 1.105, reading as follows:

§ 1.104 Drugs; statement of ingredients.

(a) The ingredient information required by section 502(e) of the Federal Food, Drug, and Cosmetic Act shall appear together without any intervening written, printed, or graphic matter, except the proprietary names of ingredients, which may be included with the listing of established names, and such statements as "Warning—May be habit forming" that are specifically required for certain ingredients by the act or regulations in this chapter.

(b) The term "ingredient" applies to any substance in the drug, whether added to the formulation as a single substance or in admixture with other substances.

(c) The labeling of a drug may be misleading by reason (among other reasons) of:

(1) The order in which the names of the ingredients present in the drug appear in the labeling, or the relative prominence otherwise given such names.

(2) Failure to reveal the proportion of, or other fact with respect to, an ingredient present in such drug, when such proportion or other fact is material in the light of the representation that such ingredient is present in such drug.

(3) The employment of a fanciful proprietary name for a drug or ingredient in such a manner as to imply that the drug or ingredient has some unique effectiveness or composition when, in fact, the drug or ingredient is a common substance, the limitations of which are readily recognized when the drug or ingredient is listed by its established name.

(4) The featuring in the labeling of inert or inactive ingredients in a manner that creates an impression of value greater than their true functional role in the formulation.

(5) Designation of a drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient.

(d) (1) If the drug is in tablet or capsule form or other unit dosage form, any statement of the quantity of an ingredient contained therein shall express the quantity of such ingredient in each such unit. If the drug is not in unit dosage form, any statement of the quantity of an ingredient contained therein shall express the amount of such ingredient in a specified unit of weight or measure of the drug, or the percentage of such ingredient in such drug. Such statements shall be in terms that are informative to licensed practitioners, in the case of a prescription drug, and to the layman, in the case of a nonprescription drug.

(2) A statement of the percentage of an ingredient in a drug shall, if the term "percent" is used without qualification, mean percent weight-in-weight, if the ingredient and the drug are both solids, or if the ingredient is a liquid and the drug is a solid; percent weight in volume at 68° F. (20° C.), if the ingredient is a solid and the drug is a liquid; and percent volume in volume at 68° F. (20° C.), if both the ingredient and the drug are liquids, except that alcohol shall be stated in terms of percent volume of absolute alcohol at 60° F. (15.56° C.).

(e) A derivative or preparation of a substance named in section 502(e) of the act is an article derived or prepared from such substance by any method, including actual or theoretical chemical action.

(f) If an ingredient is a derivative or preparation of a substance specifically named in section 502(e) of the act and the established name of such ingredient does not indicate that it is a derivative or preparation of the parent substance named in section 502(e) of the act, the labeling shall, in conjunction with the listing of the established name of such ingredient, declare that such article is a derivative or preparation of such parent substance.

(g) (1) If the label or labeling of a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation, shall accompany each appearance of such proprietary name or designation. The established name shall be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as "brand of," preceding the established name, or by brackets surrounding the established name.

(2) The established name shall be printed in letters that are at least half

as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features.

(h) (1) In the case of a prescription drug containing two or more active ingredients, if the label bears a proprietary name or designation for such mixture and there is no established name corresponding to such proprietary name or designation, the quantitative ingredient information required on the label by section 502(e) of the act shall be placed in direct conjunction with the most prominent display of the proprietary name or designation. The prominence of the quantitative ingredient information shall bear a reasonable relationship to the prominence of the proprietary name.

(2) If the drug is packaged in a container too small to bear the quantitative ingredient information on the main display panel, the quantitative ingredient information required by section 502(e) of the act may appear elsewhere on the label, even though the proprietary name or designation appears on the main display panel of the label; but side- or back-panel placement shall in this case be so arranged and printed as to provide size and prominence of display reasonably related to the size and prominence of the front-panel display.

(i) A drug packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information required for compliance with section 502(e)(1)(A)(ii) and (B) of the act shall be exempt from compliance with those clauses: *Provided,* That:

(1) The label bears:

(i) The proprietary name of the drug;

(ii) The established name, if such there be, of the drug;

(iii) An identifying lot or control number; and

(iv) The name of the manufacturer, packer, or distributor of the drug; and

(2) All the information required to appear on the label by the act and the regulations in this chapter appears on the carton or other outer container or wrapper if such carton, outer container, or wrapper has sufficient space to bear such information, or such complete label information appears on a leaflet with the package.

§ 1.105 Prescription-drug advertisements.

(a) (1) The ingredient information required by section 502(n) of the Federal Food, Drug, and Cosmetic Act shall appear together, without any intervening written, printed, or graphic matter, except the proprietary names of ingredients, which may be included with the listing of established names.

(2) The order of listing of ingredients in the advertisement shall be the same as the order of listing of ingredients on the label of the product, and the information presented in the advertisement concerning the quantity of each such ingredient shall be the same as the corresponding information on the label of the product.

(3) The advertisement shall not employ a fanciful proprietary name for the drug or any ingredient in such a manner as to imply that the drug or ingredient has some unique effectiveness or composition, when, in fact, the drug or ingredient is a common substance, the limitations of which are readily recognized when the drug or ingredient is listed by its established name.

(4) The advertisement shall not feature inert or inactive ingredients in a manner that creates an impression of value greater than their true functional role in the formulation.

(5) The advertisement shall not designate a drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient.

(b) (1) If an advertisement for a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation, shall accompany each appearance of such proprietary name or designation. The established name shall be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as "brand of," preceding the established name, or by brackets surrounding the established name.

(2) The established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features.

(c) In the case of a prescription drug containing two or more active ingredients, if the advertisement bears a proprietary name or designation for such mixture and there is no established name corresponding to such proprietary name or designation, the quantitative ingredient information required in the advertisement by section 502(n) of the act shall be placed in direct conjunction with the most prominent display of the proprietary name or designation. The prominence of the quantitative ingredient information shall bear a reasonable relationship to the prominence of the proprietary name.

(d) (1) If the advertisement employs one proprietary name or designation to refer to a combination of active ingredients present in more than one preparation (the individual preparations differing from each other as to quantities of active ingredients and/or the form of the finished preparation) and there is no established name corresponding to such proprietary name or designation, a listing showing the established names of the active ingredients shall be placed in direct conjunction with the most prominent display of such proprietary name or designation. The prominence of this listing of active ingredients shall bear a reasonable relationship to the prominence of the proprietary name and the relationship between such proprietary name or designation, and the listing of active ingredients shall be made clear by use of such phrase as "brand of," preceding the listing of active ingredients.

(2) The advertisement shall prominently display the name of at least one specific dosage form and shall have the quantitative ingredient information required by section 502(n) of the act in direct conjunction with such display. If other dosage forms are listed in the advertisement, the quantitative ingredient information for such dosage forms shall appear in direct conjunction and in equal prominence with the most prominent listing of the names of such dosage forms.

(e) A brief summary relating to side effects, contraindications, and effectiveness shall be presented in any prescription-drug advertisement that provides any information regarding indications or dosage recommendations. This summary shall fairly show the effectiveness of the drug in the conditions for which it is recommended in the advertisement, together with a showing of those side effects and contraindications that are pertinent with respect to the uses recommended or suggested in the advertisement and any other use or uses for which the dosage form advertised is commonly prescribed. A fair balance shall be made in presenting the information on effectiveness and that on side effects and contraindications; such fair balance shall be achieved even if small size of the advertisement limits the total amount of information presented.

(f) An advertisement for a prescription drug covered by an approved new-drug application shall not recommend nor suggest any use that is not in the labeling accepted in the approved new-drug application. The advertisement shall present information from the approved new-drug application labeling concerning those side effects and contraindications that are pertinent with respect to the uses recommended or suggested in the advertisement and any other use or uses for which the dosage form advertised is commonly prescribed.

(g) An advertisement for a prescription drug subject to certification shall not recommend nor suggest any use that is not in the labeling covered by the certification or covered by the applicable certification regulations or regulations providing for exemption from certification. The advertisement shall present information from such labeling covered by the certification, or the applicable certification regulations or regulations providing for exemption from certification, concerning those side effects and contraindications that are pertinent with respect to the uses recommended or suggested in the advertisement and any other use or uses for which the dosage form advertised is commonly prescribed.

(h) In the case of a prescription drug not subject to the new-drug provisions or the certification provisions, an adver-

tisement may recommend use of the drug only for those purposes for which the article is generally recognized as safe and effective by medical experts or for those purposes for which the article is generally recognized as safe by medical experts and for which there exists substantial evidence, consisting of adequate and well-controlled investigations, including clinical investigations, by medical experts, on the basis of which it can fairly and responsibly be concluded that the drug is effective for such purposes. The advertisement shall present information concerning those side effects and contraindications that are pertinent with respect to the uses recommended or suggested in the advertisement and for any other use or uses for which the dosage form advertised is commonly prescribed.

(i) The information concerning side effects and contraindications in an advertisement for a prescription drug shall appear in reasonably close association with the information concerning effectiveness and shall have the same relative degree of prominence as the information concerning effectiveness, taking into account all pertinent factors, including typography, layout, contrast, and other printing features.

(j) (1) No advertisement concerning a prescription drug may be disseminated without prior approval by the Food and Drug Administration if use of the drug may cause fatalities or serious damage and information concerning the possibility that the drug may cause fatalities or serious damage is of recent origin or has not been widely publicized in medical literature. In such case, the sponsor of the drug will be notified by the Food and Drug Administration by certified mail that advertisements for the drug must be approved before dissemination.

(2) Within a reasonable time after information concerning the possibility that a drug may cause fatalities or serious damage has been widely publicized in medical literature, the Food and Drug Administration shall notify the sponsor of the drug by mail that prior approval of advertisements for the drug is no longer necessary.

(3) Dissemination of an advertisement not in compliance with this paragraph shall be deemed to be an act that causes the drug to be misbranded under section 502(n) of the act.

(4) Any advertisement may be submitted to the Food and Drug Administration prior to publication for comment. If the advertiser is notified that the submitted advertisement is not in violation and, at some subsequent time, the Food and Drug Administration changes its opinion, the advertiser will be so notified and will be given a reasonable time for correction before any regulatory action is taken under this section. Notification to the advertiser that a proposed advertisement is or is not considered to be in violation shall be in written form.

(k) An advertisement issued or caused to be issued by the manufacturer, packer, or distributor of the drug promoted by the advertisement and which is not in compliance with section 502(n) of the act and the applicable regulations thereunder shall cause stocks of such drug in possession of the person responsible for issuing or causing the issuance of the advertisement, and stocks of the drug distributed by such person and still in the channels of commerce, to be misbranded under section 502(n) of the act.

(l) Brochures, mailing pieces, detailing pieces, file cards, bulletins, price lists, catalogs, house organs, literature reprints, and similar pieces of printed matter concerning a drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor, including reference publications for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug, are regarded as labeling not subject to section 502(n) of the act but subject to the "full disclosure" labeling requirement of § 1.106(b) or (c), as well as the labeling requirements of § 1.104.

Effective date. This order shall become effective upon publication in the FEDERAL REGISTER.

(Secs. 502 (e), (n), 701(a), 52 Stat. 1050, 1051, 1055; 21 U.S.C. 352 (e), (n), 371(a))

Dated: June 12, 1963.

GEO. P. LARRICK,
Commissioner of Food and Drugs.

[F.R. Doc. 63-6334; Filed, June 19, 1963; 8:45 a.m.]

SUBCHAPTER C—DRUGS

PART 130—NEW DRUGS

The Commissioner of Food and Drugs has considered the views and comments submitted in response to the notice of proposed rule making published in the FEDERAL REGISTER of February 14, 1963 (28 F.R. 1449), and has concluded that the regulations proposed, with changes as shown, should be adopted, effective as of the date of publication.

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130.31 Judicial review.
130.32 Confidentiality of information contained in new-drug applications.
130.33 Notice of approval.
310.34 Notice of withdrawal of approval of application.

Subpart B—Drugs Exempted From Prescription—Dispensing Requirements

130.101 Prescription-exemption procedure.
130.102 Exemption for certain drugs limited by new-drug applications to prescription sale.

AUTHORITY: §§ 130.1 to 130.102 issued under secs. 503, 505, 701, 52 Stat. 1051, 1052, 1055, as amended; 21 U.S.C. 353, 355, 371.

CROSS REFERENCES: For other regulations in this chapter concerning new drugs, see also §§ 1.106, 3.45, 3.511, 3.512, and 121.7.

Subpart A—Procedural and Interpretative Regulations

§ 130.1 Definitions and interpretations.

(a) As used in this part, the term "act" means the Federal Food, Drug, and Cosmetic Act approved June 25, 1938 (52 Stat. 1040 et seq., as amended; 21 U.S.C. 301–392).

(b) "Department" means the Department of Health, Education, and Welfare.

(c) "Secretary" means the Secretary of Health, Education, and Welfare.

(d) "Commissioner" means the Commissioner of Food and Drugs.

(e) The term "person" includes individuals, partnerships, corporations, and associations.

(f) The definitions and intepretations of terms contained in section 201 of the act shall be applicable to such terms when used in the regulations in this part.

(g) "New-drug substance" means any substance that, when used in the manufacture, processing, or packing of a drug, causes that drug to be a new drug, but does not include intermediates used in the synthesis of such substance.

(h) The newness of a drug may arise by reason (among other reasons) of:

(1) The newness for drug use of any substance which composes such drug, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component.

(2) The newness for drug use of a combination of two or more substances, none of which is a new drug.

(3) The newness for drug use of the proportion of a substance in a combination, even though such combination containing such substance in other proportion is not a new drug.

(4) The newness of use of such drug in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the body, even though such drug is not a new drug when used in another disease or to affect

another structure or function of the body.

(5) The newness of a dosage, or method or duration of administration or application, or other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug when used in other dosage, or other method or duration of administration or application, or different condition, is not a new drug.

§ 130.2 Biologics; products subject to license control.

A new drug shall not be deemed to be subject to section 505 of the act if it is a drug licensed under the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended; 42 U.S.C. 201 et seq.) or under the animal-virus-serum-toxin law of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 et seq.)

§ 130.3 New drugs for investigational use; exemptions from section 505(a).

[Regulations under this section were published in the FEDERAL REGISTER of January 8, 1963 (28 F.R. 179) and are not changed.]

§ 130.4 Applications.

(a) Applications to be filed under the provisions of section 505(b) of the act shall be submitted in triplicate. If any part of the application is in a foreign language, an accurate and complete English translation shall be appended to such part; translations of literature printed in a foreign language shall be accompanied by copies of the original publication. If the applicant does not reside or maintain a place of business within the United States or any territory or possession of the United States, the application shall be countersigned by a duly authorized attorney, agent, or other representative of the applicant who resides in the United States.

(b) Pertinent information may be incorporated in, and will be considered as part of, an application on the basis of specific reference to such information, including information submitted under the provisions of § 130.3, in the files of the Food and Drug Administration. However, any reference to information furnished by a person other than the applicant may not be considered unless use of such information is authorized in a written statement signed by the person who submitted it.

(c) Applications shall be submitted in the following form:

Form FD-356—Rev. 1963
Department of Health, Education, and Welfare, Food and Drug Administration

ORIGINAL ☐ OR SUPPLEMENTAL ☐ APPLICATION

Name of applicant _____
Address _____
Date _____
Name of new drug _____
_____
(If this is a supplemental application see Item 8)

To the Secretary of Health, Education, and Welfare,
For the Commissioner of Food and Drugs,
Washington 25, D.C.
Dear Sir:

The undersigned _____, submits this application with respect to a new drug pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act.

Attached hereto, in triplicate, and constituting a part of this application are the following:

1. Full reports of investigations that have been made to show whether or not the drug is safe for use and effective in use.

a. An application may be refused unless it contains full reports of adequate tests by all methods reasonably applicable to show whether or not the drug is safe and effective for use as suggested in the proposed labeling and includes all the following:

i. Detailed reports of the preclinical investigations, including studies made on laboratory animals, in which the methods used and the results obtained are clearly set forth. Such information should include identification of the person who conducted each investigation, a statement of where the investigations were conducted, and where the underlying data are available for inspection. The animal studies may not be considered adequate unless they give proper attention to the conditions of use recommended in the proposed labeling for the drug such as, for example, whether the drug is for short- or long-term administration or whether it is to be used in infants, children, pregnant women, or premenopausal women.

ii. Reports of all clinical tests sponsored by the applicant or received or otherwise obtained by the applicant should be attached. These reports should include adequate information concerning each subject treated with the drug or employed as a control, including age, sex, conditions treated, dosage, frequency of administration of the drug, results of all relevant clinical observations and laboratory examinations made, full information concerning any other treatment given previously or concurrently, and a full statement of adverse effects and useful results observed, together with an opinion as to whether such effects or results are attributable to the drug under investigation and a statement of where the underlying data are available for inspection. Ordinarily, the reports of clinical studies will not be regarded as adequate unless they include reports from more than one independent, competent investigator who maintain adequate case histories of an adequate number of subjects, designed to record observations and permit evaluation of any and all discernible effects attributable to the drug in each individual treated and comparable records on any individuals employed as controls. Except when the disease for which the drug is being tested occurs with such infrequency in the United States as to make testing impractical, some of the investigations should be performed by competent investigators within the United States.

iii. All information pertinent to an evaluation of the safety and effectiveness of the drug received or otherwise obtained by the applicant from any source, including information derived from other investigations or commercial marketing (for example, outside the United States), or reports in the scientific literature, involving the drug that is the subject of the application or pertinent information about any relevantly related drug. An adequate summary may be acceptable in lieu of a reprint of a published article which only supports other data submitted. Include any evaluation of the safety or effectiveness of the drug that has been made by the applicant's medical department, expert committee, or consultants.

iv. If the drug is a combination of previously investigated or marketed drugs, an adequate summary of preexisting information from preclinical and clinical investigation and experience with its components, including all reports received or otherwise obtained by the applicant suggesting side effects, contraindications, and ineffectiveness in use of such components. Such summary should include an adequate bibliography of publications about the components and may incorporate by reference information concerning such components previously submitted by the applicant to the Food and Drug Administration.

b. An application may be refused unless it includes substantial evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling.

c. The complete composition and/or method of manufacture of the new drug used in each submitted report of investigation should be shown to the extent necessary to establish its identity, strength, quality, and purity if it differs from the description in item 2, 3, or 4 of the application in any way that would bias an evaluation of the report.

d. An application shall include a complete list of the names and post office addresses of all investigators who received the drug. (This may be incorporated in whole or in part by reference to information submitted under the provisions of § 130.3.)

e. Explain any omission of reports from any investigator to whom the investigational drug has been made available. The unexplained omission of any reports of investigations made with the new drug by the applicant, or submitted to him by an investigator, or the unexplained omission of any pertinent reports of investigations or clinical experience received or otherwise obtained by the applicant from published literature or other sources, that would bias an evaluation of the safety of the drug or its effectiveness in use constitutes grounds for the refusal or withdrawal of the approval of an application.

2. A full list of the articles used as components of the drug. This list should include all substances used in the synthesis, extraction, or other method of preparation of any new-drug substance, and in the preparation of the finished dosage form, regardless of whether they undergo chemical change or are removed in the process. Each substance should be identified by its established name, if any, or complete chemical name, using structural formulas when necessary for specific identification. If any proprietary preparation is used as a component, the proprietary name should be followed by a complete quantitative statement of composition. Reasonable alternatives for any listed substance may be specified.

3. A full statement of the composition of the drug. The statement shall set forth the name and amount of each ingredient, whether active or not, contained in a stated quantity of the drug in the form in which it is to be distributed, as for example, amount per tablet or per milliliter, and a batch formula representative of that to be employed for the manufacture of the finished dosage form. All components should be included in the batch formula regardless of whether they appear in the finished product. Any calculated excess of an ingredient over the label declaration should be designated as such and percent excess shown. Reasonable variations may be specified.

4. A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug. Included in this description should be full information with respect to any new-drug substance and to the new-drug dosage form as follows, in sufficient detail to permit evaluation of the adequacy of the described methods of manufacture, processing, and packing and the described facilities and controls to determine and preserve the identity, strength, quality, and purity of the drug:

a. A description of the physical facilities including building and equipment used in manufacturing, processing, packaging, labeling, storage, and control operations.

b. A description of the qualifications, including educational background and experience, of the technical and professional personnel who are responsible for assuring that the drug has the safety, identity, strength, quality, and purity it purports or is represented to possess, and a statement of their responsibilities.

c. The methods used in the synthesis, extraction, isolation, or purification of any new-drug substance. When the specifications and controls applied to such substance are inadequate in themselves to determine its identity, strength, quality, and purity, the methods should be described in sufficient detail, including quantities used, times, temperatures, pH, solvents, etc., to determine these characteristics. Alternative methods or variations in methods within reasonable limits that do not affect such characteristics of the substance may be specified.

d. Precautions to assure proper identity, strength, quality, and purity of the raw materials, whether active or not, including the specifications for acceptance and methods of testing for each lot of raw material.

e. Whether or not each lot of raw materials is given a serial number to identify it, and the use made of such numbers in subsequent plant operations.

f. If the applicant does not himself perform all the manufacturing, processing, packaging, labeling, and control operations for any new-drug substance or the new-drug dosage form, his statement identifying each person who will perform any part of such operations and designating the part; and a signed statement from each such person fully describing, directly or by reference, the methods, facilities, and controls in his part of the operation.

g. Method of preparation of the master formula records and individual batch records and manner in which these records are used.

h. The instructions used in the manufacturing, processing, packaging, and labeling of each dosage form of the new drug, including any special precautions observed in the operations.

i. Adequate information with respect to the characteristics of and the test methods employed for the container, closure, or other component parts of the drug package to assure their suitability for the intended use.

j. Number of individuals checking weight or volume of each individual ingredient entering into each batch of the drug.

k. Whether or not the total weight or volume of each batch is determined at any stage of the manufacturing process subsequent to making up a batch according to the formula card and if so at what stage and by whom it is done.

l. Precautions to check the actual package yield produced from a batch of the drug with the theoretical yield. This should include a description of the accounting for such items as discards, breakage, etc., and the criteria used in accepting or rejecting batches of drugs in the event of an unexplained discrepancy.

m. Precautions to assure that each lot of the drug is packaged with the proper label and labeling, including provisions for labeling storage and inventory control.

n. The analytical controls used during the various stages of the manufacturing, processing, packaging, and labeling of the drug, including a detailed description of the collection of samples and the analytical procedures to which they are subjected. The analytical procedures should be capable of determining the active components within a reasonable degree of accuracy and of assuring the identity of such components. If the article is one that is represented to be sterile, the same information with regard to the manufacturing, processing, packaging, and the collection of samples of the drug should be given for sterility controls. Include the standards used for acceptance of each lot of the finished drug.

o. An explanation of the exact significance of any batch control numbers used in the manufacturing, processing, packaging, and labeling of the drug, including such control numbers that may appear on the label of the finished article. State whether these numbers enable determination of the complete manufacturing history of the product. Describe any methods used to permit determination of the distribution of any batch if its recall is required.

p. A complete description of, and data derived from, studies of the stability of the drug, including information showing the suitability of the analytical methods used. Describe any additional stability studies underway or contemplated. Stability data should be submitted for any new-drug substance, for the finished dosage form of the drug in the container including a multiple-dose container in which it is to be marketed, and if it is to be put into solution at the time of dispensing, for the solution prepared as directed. If the data indicate that an expiration date is needed to preserve the identity, strength, quality, and purity of the drug until it is used, a statement of an expiration date.

q. Additional procedures employed which are designed to prevent contamination and otherwise assure proper control of the product.

(An application may be refused unless it includes adequate information showing that the methods used in, and the facilities and controls used for, the manufacturing, processing, and packaging of the drug are adequate to preserve its identity, strength, quality and purity in conformity with good manufacturing practice and identifies each establishment, showing the location of the plant conducting these operations.)

5. Samples of the drug and articles used as components, as follows:

a. The following samples shall be submitted with the application or as soon thereafter as they become available. Each sample shall consist of four identical, separately packaged subdivisions, each containing at least three times the amount required to perform the laboratory test procedures described in the application to determine compliance with its control specifications for identity and assays:

i. A representative sample or samples of the finished dosage form(s) proposed in the application and employed in the clinical investigations and a representative sample or samples of each new-drug substance, as defined in § 130.1(g), from the batch(es) employed in the production of such dosage form(s).

ii. A representative sample or samples of finished market packages of each dosage form of the drug prepared for initial marketing, and if any such sample is not from a commercial-scale production batch, in addition such a sample from a representative commercial-scale production batch; and a representative sample or samples of each new-drug substance, as defined in § 130.1(g), from the batch(es) employed in the production of such dosage form(s). *Provided, however,* That in the case of medicated feeds marketed in large packages the sample should contain only three times a sufficient quantity of the medicated feed to allow for performing the control tests for drug identity and assays.

iii. A sample or samples of any reference standard and blank used in the procedures described in the application for assaying each new-drug substance and other assayed components of the finished drug; *Provided, however,* That samples of reference standards recognized in the official United States Pharmacopeia or The National Formulary need not be submitted unless requested.

b. Additional samples shall be submitted on request.

c. Each of the samples submitted shall be appropriately packaged and labeled to preserve its characteristics; to identify the material and the quantity in each subdivision of the sample, and to identify each subdivision with the name of the applicant and the new-drug application to which it relates.

d. There shall be included a full list of the samples submitted pursuant to item 5a; a statement of the additional samples that will be submitted as soon as available; and, with respect to each sample submitted, full information with respect to its identity, the origin of any new-drug substance contained therein (including in the case of new-drug substances, a statement whether it was produced on a laboratory, pilot-plant, or full-production scale) and detailed results of all laboratory tests made to determine the identity, strength, quality, and purity of the batch represented by the sample, including assays. Include for any reference standard a complete description of its preparation and the results of all laboratory tests on it. If the test methods used differed from those described in the application, full details of the methods employed in obtaining the reported results shall be submitted.

e. The requirements of item 5a may be waived in whole or in part on request of the applicant or otherwise when any such samples are not necessary.

6. Each copy of the application shall contain three copies of each label and all other labeling to be used for the drug.

a. Each label, or other labeling, should be clearly identified to show its position on, or the manner in which it accompanies, the market package.

b. The labeling on or within the retail package should include adequate directions for use by the layman under all the conditions for which the drug is intended for lay use, or is to be prescribed, recommended, or suggested in any labeling or advertising sponsored by or on behalf of the applicant and directed to laymen.

c. If the drug is limited in its labeling to use under the professional supervision of a practitioner licensed by law to administer it, its labeling should bear information for use under which such practitioners can use the drug for the purposes for which it is intended, including all the purposes for which it is to be advertised or represented, in accord with § 1.106 (b) or (c).

d. If no established name exists for a new-drug substance, the application shall propose a nonproprietary name for use as the established name for the substance.

e. Typewritten or other draft labeling copy may be submitted for preliminary consideration of an application. An application will not ordinarily be approved prior to the submission of the final printed label and labeling of the drug. No application may be approved if the labeling is false or misleading in any particular.

(If the article is a prescription drug, copies of proposed advertising may be submitted optionally for comment or approval.)

7. State whether the drug is (or is not) limited in its labeling and by this application to use under the professional supervision of a practitioner licensed by law to administer it.

8. If this is a supplemental application, full information on each proposed change concerning any statement made in the approved application.

(After an application is approved, a supplemental application may propose changes. A supplemental application may omit statements made in the approved application concerning which no change is proposed. A supplemental application should be submitted for any change beyond the variations provided for in the application (including changes in the scale of production such as from pilot-plant to production batch) that may alter the conditions of use, the labeling, the safety, effectiveness, identity, strength, quality, or purity of the drug or the adequacy of manufacturing methods, facilities, or controls to preserve them. Any mailing or promotional piece used after the drug is placed on the market is labeling requiring a supplemental application if it deviates in any significant respect from the approved labeling. When necessary for the safety or effectiveness of the drug, a supplemental application shall specify a period of time within which the proposed change will be made. If a material change is made in the components, composition, manufacturing methods, facilities or controls, or in the labeling or advertising from the representations in an approved application for a new drug, and the drug is marketed before a supplement is approved for such change, approval of the application may be suspended or withdrawn as provided in section 505(e) of the act. The submission of a supplemental new-drug application is not required for changes made in the new drug, or in its labeling, or in the manufacturing facilities or controls under which it is produced, that are not significant from the standpoint of safety or effectiveness. The holder of an approved new-drug application should submit to the Food and Drug Administration, in writing, full details of any proposed change or changes, and he will be notified in writing whether the approval of a supplement application is required for such change or changes. This includes all mailing and promotional pieces that are to be used after the new drug has been placed on the market. A supplemental application is not required when the article is no longer a new drug under the labeling submitted in the new-drug application, unless the proposed change itself causes it to become a new drug.)

9. It is understood that the labeling and advertising for the drug will prescribe, recommend, or suggest its use only under the conditions stated in the labeling which is part of this application; and if the article is a prescription drug, it is understood that any labeling which furnishes or purports to furnish information for use or which prescribes, recommends, or suggests a dosage for use of the drug will also contain substantially the same information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, any relevant hazards, contraindications, side effects, and precautions, contained in the labeling which is part of this application. It is understood that all representations in this application apply to the drug produced until an approved supplement to the application provides for a change or the applicant is notified in writing by the Food and Drug Administration that a supplemental application is not required for the change, or the article is no longer a new drug.

Very truly yours,

_____
(Applicant)

Per _____

_____
(Indicate authority)

(1) This application must be signed by the applicant or by an authorized attorney, agent, or official. If the applicant or such authorized representative does not reside or have a place of business within the United States, the application must also furnish the name and post office address of and must be countersigned by an authorized attorney, agent, or official residing or maintaining a place of business within the United States. The data specified under the several numbered headings should be on separate sheets or sets of sheets, suitably identified. The sample of the drug, if sent under separate cover, should be addressed to the attention of the Division of New Drugs or the Division of Veterinary Medicine and identified on the outside of the shipping package with the name of the applicant and the name of the drug as shown on the application.

(2) The applicant will be notified of the date on which his application is filed. An incomplete application, or one which has not been submitted in triplicate, will be retained but not filed as an application provided for in section 505(b) of the act. The applicant will be notified in what respect his application is incomplete.

(3) All applications and correspondence should be submitted in triplicate.

§ 130.5 Reasons for refusing to file applications.

(a) An application shall not be considered complete and will not be filed as a new-drug application within the meaning of section 505(b) of the act if it does not contain complete and accurate English translations of any pertinent part in a foreign language, if fewer than three copies are submitted, or if it is incomplete on its face in that it does not contain all the matter required by section 505(b) (1), (2), (3), (4), (5), and (6) of the act or by the new-drug application form contained in § 130.4(c), or on its face the information concerning such matter is so inadequate that the application is clearly not approvable.

(b) An application will not be accepted for filing if:

(1) The drug is to be manufactured, prepared, propagated, compounded, or processed in whole or in part in any State in an establishment that has not been registered or exempted from registration under the provisions of section 510 of the act.

(2) The applicant does not reside or maintain a place of business within the United States and the application has not been countersigned by an attorney, agent, or other representative of the applicant, which representative resides in the United States and has been duly authorized to act on behalf of the applicant and to receive communications on all matters pertaining to the application.

(3) The new drug is a drug subject to licensing under the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended; 42 U.S.C. 201 et seq.) or under the animal-virus-serum toxin law of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 et seq.)

(c) The applicant will be promptly notified of such nonacceptance and the reason therefor and, in case of incompleteness or inadequacy as to matter required by any clause of section 505(b) of the act or of the new-drug application form, such clause shall be specified. Otherwise, the date on which an application is received will be considered to be the date on which such application is filed, and the applicant will be notified of such date.

(d) If an applicant disputes the finding that his application is incomplete or inadequate, he may make written request to file the application over protest. In such case, the application shall be reevaluated, and within 30 days of the date of receipt of such written request, the application shall be approved, or the applicant shall be given written notice of an opportunity for a hearing on the question whether the application is approvable.

§ 130.6 Comment on applications.

(a) After the application has been studied, the applicant will be furnished comment on any apparent deficiencies in the data submitted or on the need for any additional data or changes in the application to facilitate its consideration.

(b) When the description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug appears adequate on its face, but it is not feasible to reach a conclusion as to the safety and effectiveness of the drug solely from consideration of this description, the applicant may be notified that an inspection is required to verify their adequacy.

(c) Withdrawal of an application may be suggested when it is found that additional evidence is required to support a finding that the drug is safe or effective or that the methods, facilities, and controls used in manufacturing, processing, and packing the drug are adequate.

(d) On the basis of preliminary consideration of an application or supplemental application containing typewritten or other draft labeling in lieu of final printed labeling, an applicant may be informed that such application is approvable when satisfactory final printed labeling identical in content to such draft copy is submitted.

§ 130.7 Amended applications.

The applicant may submit an amendment to an application that is pending, but in the case of a substantive amendment, the unamended application may be considered as withdrawn and the amended application may be considered resubmitted on the date on which the amendment is received by the Food and Drug Administration. The applicant will be notified of such date.

§ 130.8 Withdrawal of applications without prejudice.

The applicant may at any time withdraw his pending application from consideration as a new-drug application upon written notification to the Food and Drug Administration. Such withdrawal may be made without prejudice to a future filing. Upon resubmission, the time limitation will begin to run from the date the resubmission is received by the Food and Drug Administration. The application itself will be retained by the

Food and Drug Administration although it is considered withdrawn, but the applicant shall be furnished a copy at cost, on request.

§ 130.9 Supplemental applications.

(a) After an application is approved, a supplemental application may propose changes. A supplemental application may omit statements made in the approved application concerning which no change is proposed. A supplemental application should be submitted for any change beyond the variations provided for in the application (including changes in the scale of production, such as from pilot-plant to production batch), that may alter the conditions of use, the labeling, the safety, effectiveness, identity, strength, quality, or purity of the drug, or the adequacy of the manufacturing methods, facilities, or controls to preserve them. Any mailing or promotional piece used after the drug is placed on the market is labeling requiring a supplemental application if it deviates in any significant respect from the approved labeling.

(b) When necessary, for the safety or effectiveness of the drug, a supplemental application shall specify a period of time within which the proposed change will be made.

(c) If a material change is made in the components, composition, manufacturing methods, facilities or controls, or in the labeling or advertising from the representations in an approved application for a new drug, and the drug is marketed before a supplement is approved for such change, approval of the application may be suspended or withdrawn as provided in section 505(e) of the act.

(d) The submission of a supplemental new-drug application is not required for changes made in the new drug, or in its labeling, or in the manufacturing facilities or controls under which it is produced, that are not significant from the standpoint of safety or effectiveness. The holder of an approved new-drug application should submit to the Food and Drug Administration, in writing, full details of any proposed change or changes, and he will be notified in writing whether the approval of a supplemental application is required for such change or changes. This includes all mailing and promotional pieces that are to be used after the new drug has been placed on the market.

(e) A supplemental application is not required when the article is no longer a new drug under the labeling submitted in the new-drug application, unless the proposed change itself causes it to become a new drug.

§ 130.10 Notification of applicant of approval of application.

If the Commissioner determines that none of the grounds for denying approval specified in section 505(d) of the act applies, the applicant shall be notified in writing that the application is approved and the application shall be approved on the date of the notification.

§ 130.11 Insufficient information in application.

(a) The information contained in an application may be insufficient to determine whether a drug is safe or effective in use if it fails to include (among other things) a statement showing whether the drug is to be limited to prescription sale and exempt under section 502(f)(1) of the act from the requirement that its labeling bear adequate directions for use. If the drug is to be exempt, the information may also be insufficient if:

(1) The specimen labeling proposed fails to bear adequate information for use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to administer the drug can use the drug for the purposes for which it is intended, including all purposes for which it is to be advertised, or represented, in accordance with § 1.106 (b) or (c) of this chapter, and information concerning hazards, contraindications, side effects, and precautions, relevant with respect to any uses for which the drug is commonly prescribed.

(2) The application fails to show that the labeling and advertising of the drug will offer the drug for use only under those conditions for which it is offered in the labeling that is part of the application.

(3) The application fails to show that all labeling that furnishes or purports to furnish information for use of the drug will contain substantially the same information for use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions, which is contained in the labeling that is part of the application, in accordance with § 1.106 (b) or (c) of this chapter.

(b) The information contained in an application will be considered insufficient to determine whether a drug is safe and effective for use when there is a refusal or failure upon written notice to furnish duly authorized inspectors of the Food and Drug Administration an adequate opportunity to inspect the facilities, controls, and any record pertinent to the application.

§ 130.12 Refusal to approve the application.

(a) If the Commissioner determines upon the basis of the application, or upon the basis of other information before him with respect to the new drug, that:

(1) The investigations, reports of which are required to be submitted pursuant to section 505(b) of the act, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; or

(2) The results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; or

(3) The methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; or

(4) Upon the basis of the information submitted to the Food and Drug Administration as part of the application, or upon the basis of any other information before it with respect to such drug, it has insufficient information to determine whether such drug is safe for use under such conditions; or

(5) Evaluated on the basis of information submitted as part of the application and any other information before the Food and Drug Administration with respect to such drug, there is lack of substantial evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling; or

(6) Based on a fair evaluation of all material facts, such labeling is false or misleading in any particular;

the Commissioner shall within 180 days after the filing of the application inform the applicant in writing of his intention to issue a notice of hearing on a proposal to refuse to approve the application.

(b) Unless by the 30th day following the date of issuance of the letter informing the applicant of the intention to issue a notice of hearing, the applicant:

(1) Withdraws the application; or

(2) Waives the opportunity for a hearing; or

(3) Agrees with the Commissioner on an additional period to precede issuance of such notice of hearing,

the Commissioner shall expeditiously notify the applicant of an opportunity for a hearing on the question of whether such application is approvable as provided in § 130.14.

§ 130.13 Records and reports concerning experience on drugs for which an approval is in effect.

(a) On receiving notification that an application for a new drug is approved, the applicant shall establish and maintain records and make reports that are necessary to facilitate a determination whether there may be grounds for invoking section 505(e) of the act to suspend or withdraw approval of the application, including adequately organized and indexed files containing full reports of any information of the following kinds that has not previously been submitted as part of his application for the drug and which is received or otherwise obtained by him from any source:

(1) Clinical experience, studies, investigations, and tests conducted by the

applicant, or reported to him by any person, or reports in the scientific literature that are received or otherwise obtained by him, involving the drug that is the subject of the application or any related drug that is pertinent to the safety or effectiveness of the drug that is the subject of the application.

(2) Animal experience, studies, investigations, and tests conducted by the applicant, or reported to him by any person, or reports in the scientific literature that are received or otherwise obtained by him involving the drug that is the subject of the application or any related drug that is pertinent to the safety or effectiveness of the drug that is the subject of the application.

(3) Experience, investigation, studies, or tests involving the chemical or physical properties or any other properties of the drug, such as its behavior or properties in relation to microorganisms, including both the effects of the drug on microorganisms and the effects of microorganisms on the drug.

(4) The information required by this section shall include, when known, adequate identification of its source, including the name and post office address of the person who furnished such information.

(5) Copies of all mailing pieces and other labeling, and if it is a prescription drug all advertising, other than that contained in the application, used in promoting the drug.

(b) The applicant shall submit copies of the records and reports described in paragraph (a) of this section (except routine assay and control records), appropriately identified with the new-drug application(s) to which they relate, in triplicate to the Food and Drug Administration, as follows:

(1) Immediately upon receipt by the applicant, complete records or reports covering information of the following kinds:

(i) Information concerning any mixup in the drug or its labeling with another article.

(ii) Information concerning any bacteriological, or any significant chemical, physical, or other change or deterioration in the drug, or any failure of one or more distributed batches of the drug to meet the specifications established for it in the new-drug application.

(2) As soon as possible, and in any event within 15 working days of its receipt by the applicant, complete records or reports concerning any information of the following kinds:

(i) Information concerning any unexpected side effect, injury, toxicity, or sensitivity reaction or any unexpected incidence or severity thereof associated with clinical uses, studies, investigations, or tests, whether or not determined to be attributable to the drug, except that this requirement shall not apply to the submission of information described in a written communication to the applicant from the Food and Drug Administration as types of information that may be submitted at other designated intervals. "Unexpected" as used in this subdivision refers to conditions or developments not encountered during clinical trials of the drug, or conditions or developments occurring at a rate higher than encountered during such clinical trials.

(ii) Information concerning any unusual failure of the drug to exhibit its expected pharmacological activity.

(3) All the kinds of information described in paragraph (a) of this section, other than that submitted under the provisions of paragraph (b) (1) and (2) of this section, shall be submitted at the following intervals, unless otherwise ordered in a written communication from the Commissioner:

(i) If the drug is intended for administration to man, within intervals of 3 months beginning with the date of approval of the application during the first year following such date; within intervals of 6 months during the second year following such date; and at yearly intervals thereafter.

(ii) If the drug is intended solely for administration to animals, at intervals within 6 months beginning with the date of approval of the application during the first year following such date, and at yearly intervals thereafter.

(iii) The submitted copies of records and reports shall include all the required information that was received or otherwise obtained by the applicant during the designated intervals.

(4) On written order of the Commissioner, within the time stated in such order or agreed to by the applicant and the Commissioner, any designated records or reports containing the kinds of information described in this section.

(c) The reports submitted under the provisions of this section are not required to furnish the names and addresses of individual patients unless the applicant is notified in writing by the Food and Drug Administration that individual patient identification is required with respect to designated reports in order to permit further investigation or because there is reason to believe that such reports do not represent actual results obtained.

(d) The applicant shall upon request of any properly authorized officer or employee of the Department, at reasonable times, permit such officers to have access to and copy and verify any records and reports established and maintained under the provisions of this section.

(e) If the Food and Drug Administration finds that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with the provisions of this section, or that the applicant has refused to permit access to, or copying or verification of such records or reports, the Commissioner shall give the applicant due notice and opportunity for a hearing on the question of whether to withdraw the approval of the application, as provided in §§ 130.14 and 130.27.

(f) Upon written request of the applicant, stating reasonable grounds therefor, the Commissioner will make available any information in possession of the Food and Drug Administration of the kinds the applicant is required to maintain under the provisions of this section, except information readily available to the applicant from other sources or information which the Commissioner concludes must be considered confidential.

§ 130.14 Contents of notice of hearing.

(a) The notice to the applicant of opportunity for a hearing on a proposal by the Commissioner to refuse to approve an application or to withdraw the approval of an application will specify the grounds upon which he proposes to issue his order. On request of the applicant, the Commissioner will explain the reasons for his action. The notice of hearing will specify that the applicant has 30 days after issuance of the notice within which he is required to file a written appearance electing whether:

(1) To avail himself of the opportunity for a hearing at the place specified in the notice of hearing; or

(2) Not to avail himself of the opportunity for a hearing.

(b) If the applicant elects to accept the opportunity for a hearing by written request within 30 days after such notice, a hearing examiner will be named and he shall issue a written notice of the time and place at which the hearing shall commence, not more than 90 days after the expiration of such 30 days unless the hearing examiner and the applicant otherwise agree.

(c) The hearing will be open to the public: *Provided, however,* That if the Commissioner finds that portions of the application which serve as a basis for the hearing contain information concerning a method or process which as a trade secret is entitled to protection, the part of the hearing that involves such portions will not be public unless the respondent so specifies in his appearance.

§ 130.15 Failure to file an appearance.

If the applicant fails to file a written appearance in answer to the notice of hearing, his failure will be construed as an election not to avail himself of the opportunity for the hearing, and the Commissioner, without further notice, may enter a final order.

§ 130.16 Appearance of applicant.

If the applicant elects to avail himself of the opportunity for the hearing, he may appear in person or by counsel. If the applicant desires to be heard through counsel, the counsel will file with the hearing examiner a written appearance.

§ 130.17 Hearing examiner.

The hearing will be conducted by a hearing examiner appointed as provided in the Administrative Procedure Act (60 Stat. 235; 5 U.S.C. 1002 et seq.) and designated for conducting the hearing. Any such designation may be made or revoked by the Commissioner at any time. Hearings will be conducted in an informal but orderly manner in accordance with these regulations and the requirements of the Administrative Procedure Act. The hearing examiner will have the power to administer oaths and affirmations, to rule upon offers of proof and the admissibility of evidence, to re-

ceive relevant evidence, to examine witnesses, to regulate the course of the hearing, to hold conferences for the simplification of the issues, and to dispose of procedural requests, but will not have the power to decide any motion that involves final determination of the merits of the proceeding.

§ 130.18 Prehearing and other conferences.

The hearing examiner, on his own motion or on the motion of the applicant or the Food and Drug Administration, may direct all parties or their representatives to appear at a specified time and place for a conference to consider:

(a) The simplification of the issues.

(b) The possibility of obtaining stipulations, admissions of facts, and documents.

(c) The limitation of the number of expert witnesses.

(d) The scheduling of witnesses to be called.

(e) The advance submission of all documentary evidence.

(f) Such other matters as may aid in the disposition of the proceeding.

The hearing examiner will make an order reciting the action taken at the conference, the agreements made by the parties or their representatives, and the schedule of witnesses, and limiting the issues for hearing to those not disposed of by admissions or agreements. Such order will control the subsequent course of the proceeding unless modified for good cause by subsequent order. The hearing examiner may also direct all parties and their representatives to appear at conferences at any time during the hearing with a view to simplification, clarification, or shortening the hearing.

§ 130.19 Submission of documentary evidence in advance.

(a) All documentary evidence to be offered at the hearing shall be submitted to the hearing examiner and to the parties sufficiently in advance of the offer of such documentary evidence for introduction into the record to permit study and preparation of cross-examination and rebuttal evidence.

(b) The hearing examiner after consultation with the parties at a conference called in accordance with § 130.18 shall make an order specifying the time at which documentary evidence shall be submitted. He shall also specify in his order the time within which objections to the authenticity of such documents must be made to comply with paragraph (d) of this section.

(c) Documentary evidence not submitted in advance in accordance with the requirements of paragraphs (a) and (b) of this section shall not be received in evidence in the absence of a clear showing that the offering party had good cause for his failure to produce the evidence sooner.

(d) The authenticity of all documents submitted in advance shall be deemed admitted unless written objection thereto is filed with the hearing examiner upon notice to the other parties within the time specified by the hearing examiner in accordance with paragraph (b) of this section, except that a party will be permitted to challenge such authenticity at a later time upon a clear showing of good cause for failure to have filed such written objection.

§ 130.20 Excerpts from documentary evidence.

When portions only of a document are to be relied upon, the offering party shall prepare the pertinent excerpts, adequately identified, and shall supply copies of such excerpts, together with a statement indicating the purpose for which such materials will be offered, to the hearing examiner and to the other parties. Only the excerpts, so prepared and submitted, shall be received in the record. However, the whole of the original document shall be made available for examination and for use by opposing counsel for purposes of cross-examination.

§ 130.21 Submission and receipt of evidence.

(a) Each witness shall, before proceeding to testify, be sworn or make affirmation.

(b) When necessary in order to prevent undue prolongation of the hearing, the hearing examiner may limit the number of times any witness may testify, the repetitious examination and cross-examination of witnesses, or the amount of corroborative or cumulative evidence.

(c) The hearing examiner shall admit only evidence that is relevant, material, and not unduly repetitious.

(d) Opinion evidence shall be admitted when the hearing examiner is satisfied that the witness is properly qualified.

(e) If any person objects to the admission or rejection of any evidence, or other limitation of the scope of any examination or cross-examination, he shall state briefly the grounds for such objection, and the transcript shall not include extended argument or debate thereon except as ordered by the hearing examiner. A ruling on any such objection shall be a part of the transcript, together with such offer of proof as has been made.

§ 130.22 Transcript of the testimony.

Testimony given at a hearing shall be reported verbatim. All written statements, charts, tabulations, and similar data offered in evidence at the hearing shall be marked for identification and, upon a showing satisfactory to the hearing examiner of their authenticity, relevancy, and materiality, shall be received in evidence subject to section 7(c) of the Administrative Procedure Act (5 U.S.C. 1006(c)). Exhibits shall, if practicable, be submitted in quintuplicate. In case the required number of copies are not made available, the hearing examiner shall exercise his discretion as to whether said exhibit shall be read in evidence or whether additional copies shall be required to be submitted within a time to be specified by the hearing examiner. Where the testimony of a witness refers to a statute, or to a report or document, the hearing examiner shall, after inquiry relating to the identification of such statute, report, or document, determine whether the same shall be produced at the hearing and physically be made a part of the evidence or shall be incorporated in the record by reference. Where relevant and material matter offered in evidence is embraced in a report or document containing immaterial and irrelevant matter, such immaterial and irrelevant matter shall be excluded and shall be segregated insofar as practicable, subject to the direction of the hearing examiner.

§ 130.23 Oral and written arguments.

(a) Unless the hearing examiner shall issue an announcement at the hearing authorizing oral argument before him, it shall not be permitted.

(b) The hearing examiner shall announce at the hearing a reasonable period within which the parties or their representatives may file written arguments based solely upon the evidence received at the hearing, citing the pages of the transcript of the testimony or of properly identified exhibits where such evidence occurs.

§ 130.24 Tentative order.

The hearing examiner, within a reasonable time, shall prepare tentative findings of fact and a tentative order, which shall be served upon the applicant and the Food and Drug Administration or sent to them by certified mail. If no exceptions are taken to the tentative order within 20 days or such other time specified in such order, that order shall become final.

§ 130.25 Exceptions to the tentative order.

Within 20 days or such other time specified in the tentative order, the applicant or the Food and Drug Administration may transmit exceptions to the hearing examiner, together with any briefs or argument in support thereof. If exception is taken to any tentative findings of fact, reference must be made to the pages or parts of the record relied upon, and a corrected finding of fact must be submitted. The applicant, if he files exceptions, shall state in writing whether he desires to make an oral argument.

§ 130.26 Issuance of final order.

Within a reasonable time after the filing of exceptions, or after oral argument (if such argument is requested), the Commissioner shall issue the final order in the proceeding. The order will include the findings of fact upon which it is based.

§ 130.27 Withdrawal of approval of an application.

The Commissioner shall, in writing, notify the person holding an approved new-drug application and afford an opportunity for a hearing on a proposal to withdraw approval of the application as provided in section 505(e) of the act and in accordance with the procedure in §§ 130.14 to 130.26, inclusive, if:

(a) The Secretary has suspended the approval of such application on a finding that there is an imminent hazard to the public health; or

(b) The Commissioner finds:

(1) That clinical or other experience, tests, or other scientific data show that the drug is unsafe for use under the conditions of use upon the basis of which the application was approved; or

(2) That new evidence of clinical experience, not contained in the application or not available to the Food and Drug Administration until after the application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when the application was approved, evaluated together with the evidence available when the application was approved, reveal that the drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or

(3) Upon the basis of new information before the Food and Drug Administration with respect to the drug, evaluated together with the evidence available when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or

(4) That the application contains any untrue statement of a material fact;

or

(c) The Commissioner finds:

(1) That the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under section 505(j) of the act and of §130.13, or that the applicant has refused to permit access to, or copying or verification of, such records as required; or

(2) That on the basis of new information before the Food and Drug Administration, evaluated together with the evidence available when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity; or

(3) That on the basis of new information before the Food and Drug Administration, evaluated together with the evidence available when the application was approved, the labeling of the drug, based on a fair evaluation of all material facts, is false or misleading in any particular;

and that the matter complained of was not corrected by the applicant within a reasonable time after his receipt of written notice from the Commissioner specifying the matter complained of.

(d) Any hearing following summary suspension on a finding of imminent hazard to health shall be afforded promptly and shall proceed on an expedited basis.

§ 130.28 Revocation of order refusing to approve application, or suspending or withdrawing approval of an application.

The Commissioner, upon his own initiative or upon request of an applicant stating reasonable grounds therefor, may, if he finds that the facts so require, issue an order approving an application concerning which an approval has previously been refused, suspended, or withdrawn.

§ 130.29 Service of notices and orders.

All notices and orders under this Part 130 and section 505 of the act pertaining to new-drug applications shall be served:

(a) In person by any officer or employee of the Department designated by the Commissioner; or

(b) By mailing the order by certified mail addressed to the applicant or respondent at his last known address in the records of the Food and Drug Administration.

§ 130.30 Untrue statements in application.

Among the reasons why an application may contain an untrue statement of a material fact are:

(a) Differences in:

(1) Conditions of use prescribed, recommended, or suggested by the applicant for the drug from the conditions of such use stated in the application;

(2) Articles used as components of the drug from those listed in the application;

(3) Composition of the drug from that stated in the application;

(4) Methods used in, or the facilities and controls used for, the manufacture, processing, or packing of the drug from such methods, facilities, and controls described in the application;

(5) Labeling from the specimens contained in the application;

or

(b) The unexplained omission in whole or in part, from the original application or any amendment or supplement to it, or from any record or report required under the provisions of section 505(j) of the act and § 130.13, of any information obtained from (1) investigations as to safety or effectiveness; or (2) investigations as to identity, strength, quality, or purity of the drug made by the applicant on the drug; or (3) investigations or experience with the drug, or any drug which is relevantly related to the drug that is the subject of the application available to the applicant from any source, if such information is pertinent to an evaluation of the safety, effectiveness, identity, strength, quality or purity of the drug, when such omission would bias an evaluation of the safety or effectiveness of the drug.

§ 130.31 Judicial review.

The Assistant General Counsel for Food and Drugs of the Department of Health, Education, and Welfare is hereby designated as the officer upon whom copies of petitions for judicial review shall be served. Such officer shall be responsible for filing in the court a transcript of proceedings and the record on which the final orders were based. The transcript and record shall be certified by the Commissioner.

§ 130.32 Confidentiality of information contained in new-drug applications.

(a) The Federal Food, Drug, and Cosmetic Act provides, in section 505(b), that any person may file with the Secretary an application with respect to any new drug, which shall include, among other things, a full list of the articles used as components and a full statement of the composition of such drug. These requirements apply to all components or ingredients of a new drug, whether or not they are therapeutically active. Fulfillment of these requirements may be met by submitting a full statement of the chemical or common or usual name and of the quantity of each component or ingredient of the drug. Such requirements may also be met through the inclusion in the new-drug application of a properly authorized reference to a previous application or other Food and Drug Administration file containing the relevant information.

(b) Section 301(j) of the act makes it an offense to divulge to unauthorized persons any information acquired from a new-drug application concerning any method or process that is a trade secret. Basic manufacturers sometimes submit data to the Food and Drug Administration in the form of so-called master files for the purpose of establishing the safety of ingredients that may be used in new drugs and authorize specified applicants to incorporate by reference such data in support of their applications. Such manufacturers may regard some of the data in such files as trade secrets and request the Food and Drug Administration to treat such information as confidential. The Food and Drug Administration will preserve the confidentiality of such data to the extent that it may properly do so. Because the applicant is legally responsible for the composition of the new drug and all its ingredients and may require information in the master file for judicial or administrative proceedings concerning the drug, the Food and Drug Administration will not withhold such information from the applicant when his need for it arises and he submits a written request for it. The Food and Drug Administration will inform the person who submitted the data of any such requests.

§ 130.33 Notice of approval.

When a new-drug application is approved, the Commissioner will publish an appropriate notice thereof in the FEDERAL REGISTER. Further, if a supplement to an approved new-drug application becomes necessary to add additional warnings, contraindications, or information about new side effects, the Commissioner may publish an appropriate notice thereof in the FEDERAL REGISTER. Publication may be delayed until an appropriate date related to the date of initial distribution of the drug.

§ 130.34 Notice of withdrawal of approval of application.

Where approval of a new-drug application is withdrawn by the Commissioner, he will give appropriate public notice of such action by publication in the FEDERAL REGISTER.

Subpart B—Drugs Exempted From Prescription-Dispensing Requirements

§ 130.101 Prescription-exemption procedure.

(a) *Duration of prescription requirement.* Any drug limited to prescription use under section 503(b)(1)(C) of the act remains so limited until it is exempted as provided in paragraph (b) of this section.

(b) *Prescription-exemption procedure for drugs limited by a new-drug application.* Any drug limited to prescription use under section 503(b)(1)(C) of the act shall be exempted from prescription-dispensing requirements when the Commissioner finds such requirements are not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, and he finds that the drug is safe and effective for use in self-medication as directed in proposed labeling. A proposal to exempt a drug from the prescription-dispensing requirements of section 503(b)(1)(C) of the act may be initiated by the Commissioner or by any interested person. Any interested person may file a petition seeking such exemption, stating reasonable grounds therefor, which petition may be in the form of a supplement to an approved new-drug application. Upon receipt of such a petition, or on his own initiative at any time, the Commissioner will publish a notice of proposed rule making and invite written comments. After consideration of all available data, including any comments submitted, the Commissioner may issue a regulation granting or refusing the exemption, effective on a date specified therein. Whenever the Commissioner concludes, either at the time of publication of the notice of proposed rule making or after considering the written comments submitted, that granting or refusing the exemption requires a more thorough development of the facts than is possible in a written presentation, he may call a public hearing for that purpose. The notice of such hearing shall specify the questions to be considered. As soon as practicable after completion of the hearing, the final regulation granting or refusing the exemption shall be issued, effective on a date specified therein. If the Commissioner for good cause finds (and incorporates the finding and a brief statement of the reasons therefor in a regulation) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, he may issue the final regulation forthwith.

(c) *New-drug status of drugs exempted from the prescription requirement.* A drug exempted from the prescription requirement under the provisions of paragraph (b) of this section is a "new drug" within the meaning of section 201(p) of the act until it has been used to a material extent and for a material time under such conditions.

(d) *Prescription legend not allowed on exempted drugs.* The use of the prescription caution statement quoted in section 503(b)(4) of the act, in the labeling of a drug exempted under the provisions of this section, constitutes misbranding. Any other statement or suggestion in the labeling of a drug exempted under this section, that such drug is limited to prescription use, may constitute misbranding.

§ 130.102 Exemption for certain drugs limited by new-drug applications to prescription sale.

[No changes were made in this section]

Dated: June 12, 1963.

GEO. P. LARRICK,
Commissioner of Food and Drugs.

[F.R. Doc. 63-6337; Filed, June 19, 1963; 8:45 a.m.]

PART 133—DRUGS; CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURE, PROCESSING, PACKING, OR HOLDING

In the FEDERAL REGISTER of February 14, 1963 (28 F.R. 1459), proposed regulations to establish criteria for current good manufacturing practice in the processing, packing, and holding of drugs were published. Extensive comments were received, and on the basis of these comments and other relevant information, the Commissioner of Food and Drugs has determined that the following regulations should issue. Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 501(a)(2)(B), 701(a); 52 Stat. 1050 as amended 76 Stat. 780, 781; 1055; 21 U.S.C.A. 351(a)(2)(B), 371(a)), and the authority delegated to him by the Secretary of Health, Education, and Welfare (25 F.R. 8625): *It is ordered,* That these regulations be adopted as set forth below:

DEFINITIONS

Sec.
133.1 Definitions.

FINISHED PHARMACEUTICALS; MANUFACTURING PRACTICE

133.2 Current good manufacturing practice.
133.3 Buildings.
133.4 Equipment.
133.5 Personnel.
133.6 Components.
133.7 Master formula and batch-production records.
133.8 Production and control procedures.
133.9 Product containers.
133.10 Packaging and labeling.
133.11 Laboratory controls.
133.12 Distribution records.
133.13 Stability.
133.14 Complaint files.

AUTHORITY: §§ 133.1 to 133.14 issued under secs. 501, 701; 52 Stat. 1050 as amended 76 Stat. 780, 781; 1055; 21 U.S.C.A. 351, 371.

DEFINITIONS

§ 133.1 Definitions.

(a) As used in this Part 133, "act" means the Federal Food, Drug, and Cosmetic Act, sections 201–902, 52 Stat. 1052 (21 U.S.C. 321–392), with all amendments thereto.

(b) The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable to such terms when used in the regulations in this Part 133.

FINISHED PHARMACEUTICALS; MANUFACTURING PRACTICE

§ 133.2 Current good manufacturing practice.

The criteria in §§ 133.3–133.13, inclusive, shall apply in determining whether the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or holding of a drug conform to or are operated or administered in conformity with current good manufacturing practice to assure that a drug meets the requirements of the act as to safety, and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess, as required by section 501(a)(2)(B) of the act. The regulations in this Part 133 permit the use of precision automatic mechanical or electronic equipment in the production of drugs when adequate inspection and checking procedures are used to assure proper performance.

§ 133.3 Buildings.

Buildings in which drugs are manufactured, processed, packaged, labeled, or held shall be maintained in a clean and orderly manner and shall be of suitable size, construction, and location in relation to surroundings to facilitate maintenance and operation for their intended purpose. The buildings shall:

(a) Provide adequate space for the orderly placement of equipment and materials used in any of the following operations for which it is employed, to minimize any risk of mix-ups between different drugs, their components, packaging, or labeling:

(1) The receipt, sampling, and storage of components.

(2) Any manufacturing and processing operations performed on the drug.

(3) Any packaging and labeling operations.

(4) Storage of containers, packaging materials, labeling, and finished products.

(5) Control and production-laboratory operations.

(b) Provide adequate lighting and ventilation, and when necessary for the intended production or control purposes, adequate screening, filtering, dust, humidity, temperature, and bacteriological controls, as for example, to prevent contamination of products by extraneous adulterants; to prevent the dissemination of micro-organisms from one area to another; to facilitate the sterilization of special work areas, such as those used for production of parenteral preparations; to provide suitable housing for any animals; and to avoid other conditions unfavorable to the safety and integrity of the product.

(c) Provide for adequate washing, cleaning, toilet, and locker facilities.

§ 133.4 Equipment.

Equipment used for the manufacture, processing, packaging, labeling, holding, or control of drugs shall be maintained in a clean and orderly manner and shall be of suitable design, size, construction,

and location in relation to surroundings to facilitate maintenance and operation for its intended purpose. The equipment shall:

(a) Be so constructed that any surfaces that come into contact with drugs are suitable, in that they are not reactive, additive, or absorptive to an extent that significantly affects the identity, strength, quality, or purity of the drug or its components.

(b) Be so constructed that any substances required for the operation of the equipment, such as lubricants or coolants, may be employed without hazard of becoming additive to drug products.

(c) Be constructed to facilitate adjustment, cleaning, and maintenance as necessary to assure the reliability of control procedures, to assure uniformity of production, and to assure the exclusion from drugs of contaminants, including those from previous and current manufacturing operations.

(d) Be of suitable size and accuracy for use in any intended measuring, mixing, or weighing operations.

§ 133.5 Personnel.

The key personnel involved in the manufacture and control of the drug shall have a background of appropriate education or appropriate experience or combination thereof for assuming responsibility to assure that the drug has the safety, identity, strength, quality, and purity that it purports to possess.

§ 133.6 Components.

Components used in the manufacture and processing of drugs, regardless of whether they appear in the finished product, shall be identified, stored, examined, tested, inventoried, handled, and otherwise controlled in a manner to assure that they conform to appropriate standards of identity, strength, quality, and purity, and are free of contaminants at time of use, and to provide that appropriate records are maintained of their origin, receipt, examination, testing, disposition, and use in drug manufacture or processing.

§ 133.7 Master-formula and batch-production records.

(a) For each drug product, master-formula records shall be prepared, endorsed, and dated by a competent and responsible individual and shall be independently checked, reconciled, endorsed, and dated by a second competent and responsible individual. The record shall include:

(1) The name of the product, a description of its dosage form, and a specimen or copy of the label and each other portion of the labeling contained in a retail package of the drug.

(2) The weight or measure of each ingredient per dosage unit or per unit of weight or measure of the finished drug, and a statement of the total weight or measure of any dosage unit.

(3) A complete batch formula for each batch size to be produced from the master-formula record, including a complete list of ingredients designated by names or codes sufficiently specific to indicate any special quality characteristic; an accurate statement of the weight or measure of each ingredient, regardless of whether it appears in the finished product, except that reasonable variations may be permitted in the amount of components necessary in the preparation in dosage form, provided that the variations are stated in the master formula; an appropriate statement concerning any calculated excess of an ingredient; appropriate statements of theoretical weight or measure at various stages of processing; and a statement of the theoretical yield.

(4) A description of the containers, closures, packaging, and finishing materials.

(5) Manufacturing and control instructions, procedures, specifications, special notations, and precautions to be followed.

(b) A separate batch-production and control record shall be prepared for each batch of drug produced and shall be retained for at least 2 years after distribution has been completed. The batch-production and control record shall include:

(1) An accurate reproduction of the appropriate master-formula record, checked and endorsed by a competent, responsible individual.

(2) Records of each step in the manufacturing, processing, packaging, labeling, and controlling of the batch, including dates, specific identification of each batch of components used, weights or measures of components and products in course of processing, in-process and laboratory-control results, and the endorsements of the individual actively performing or the individual actively supervising or checking each step in the operation.

(3) A batch number that permits determination of all laboratory-control procedures and results on the batch and all lot or control numbers appearing on the labels of drugs from the batch.

§ 133.8 Production and control procedures.

Production and control procedures shall include all reasonable precautions, including the following, to assure that the drugs produced have the identity, strength, quality, and purity they purport to possess.

(a) Each critical step in the process, such as the selection, weighing, and measuring of components; the addition of active ingredients during the process; weighing and measuring during various stages of the processing; and the determination of the finished yield shall be performed by a competent, responsible individual and checked by a second competent, responsible individual, or if such steps in the processing are controlled by precision automatic mechanical or electronic equipment their proper performance is adequately checked by one or more competent, responsible individuals.

(b) All containers and equipment used in producing a batch of drugs shall be clearly labeled at all times to identify fully and accurately their contents, the stage of processing, and the batch, and shall be stored and handled in a manner adequate to prevent mixups with other drugs.

(c) Equipment, utensils, and containers shall be thoroughly cleaned and previous identification removed between batches and in continuous batch operations at suitable intervals, to prevent contamination and mixups.

(d) Appropriate procedures to minimize the hazard of contamination with micro-organisms in the production of parenteral drugs, ophthalmic solutions, and any other drugs purporting to be sterile.

(e) To assure the uniformity and integrity of products, there shall be adequate in-process controls, such as checking the weights and disintegration time of tablets, checking fill of liquids, and checking the adequacy of mixing, the homogeneity of suspensions, and the clarity of solutions.

(f) Competent and responsible personnel shall check actual against theoretical yield of a batch of drug, and in the event of any significant unexplained discrepancies, key personnel shall prevent distribution of the batch in question and other associated batches of drugs that may have been involved in a mixup with it.

§ 133.9 Product containers.

Suitable specifications, test methods, cleaning procedures, and, when indicated, sterilization procedures shall be used to assure that containers, closures, and other component parts of drug packages are suitable for their intended use, in that they are not reactive, additive, or absorptive to an extent that significantly affects the identity, strength, quality, or purity of the drug, and furnish adequate protection against its deterioration or contamination.

§ 133.10 Packaging and labeling.

Packaging and labeling operations shall be adequately controlled to assure that only those drugs that have met the specifications established in the master-formula records shall be distributed; to prevent mixups between drugs during the packaging and labeling operations; to assure that correct labeling is employed for the drug; and to identify finished products with lot or control numbers that permit determination of the history of the manufacture and control of the batch of drug. Packaging and labeling operations shall:

(a) Be performed with adequate physical segregation of such operations from operations on any other drugs to avoid mixups.

(b) Provide that each type of labeling used shall be stored in a manner that avoids mixups between labelings and shall be carefully checked for identity and conformity to the labeling specified in the batch-production records.

(c) Provide adequate control of the quantities of labeling issued for use with the drug. (Competent, responsible personnel shall reconcile any discrepancy between the quantity of drug finished and the quantity of labeling issued. In the event of any significant unexplained discrepancy, key personnel shall prevent distribution of the batch in question and

other associated batches of drugs that may have been involved in a mixup.)

(d) Provide for an inspection of the facilities to be used prior to labeling a drug to assure that all the previously used labeling and other drugs have been removed.

(e) Provide for adequate examination or laboratory testing of adequately representative samples of finished products after packaging and labeling to safeguard against any error in the finishing operations, and to prevent distribution of any batch until all specified tests have been met.

§ 133.11 Laboratory controls.

Laboratory controls shall include the establishment of adequate specifications and test procedures to assure that components, drug preparations in the course of processing, and finished products conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include:

(a) The establishment of master records containing appropriate specifications for each component used in drug production and a description of the test procedures used to check them, including provision for testing adequately representative samples. Such records shall also provide for appropriate retesting of materials subject to deterioration.

(b) The establishment of appropriate specifications, when needed, for drug preparations in the course of processing, and a description of the test procedures to check them, including provision for testing adequately representative samples.

(c) The establishment of appropriate finished-product specifications and a description of laboratory test procedures to check them, including provision for testing adequately representative samples.

(d) Adequate provision for checking the identity and strength for all active ingredients of drugs, for assuring the sterility of articles purporting to be sterile, and the freedom from pyrogens of articles that should be tested for freedom from pyrogens.

(e) Adequate provision to check the reliability, accuracy, and precision of any laboratory test procedures used.

(f) A reserve sample of at least twice the quantity of drug required to conduct all the tests performed on the batch of drug shall be retained at least 2 years after distribution has been completed.

(g) Provision for complete records of all data concerning laboratory tests performed, including the dates and endorsements of individuals making the tests, and provision for specifically relating the tests to each batch of drug to which they apply. Such records shall be retained for at least 2 years after distribution has been completed.

§ 133.12 Distribution records.

Complete records shall be maintained of the distribution of each batch of drug in a manner that will facilitate its recall if necessary. Such records shall be retained for at least 2 years after distribution has been completed, and shall include the name and address of the consignee, the date and quantity shipped, and the lot or control numbers identifying the batch of drug.

§ 133.13 Stability.

Adequate provision shall be made for testing the stability of components, drug preparations in the course of processing, when needed, and finished drugs. Such stability tests shall:

(a) Make adequate provision for determining the reliability and specificity of stability test methods employed.

(b) Make adequate provision to determine the stability of products in the containers in which they are marketed to assure, among other things, that the container is suitable, in that it is not reactive, additive, or adsorptive to an extent that significantly affects the identity, strength, quality, or purity of the drug.

(c) Provide for stability studies of any solutions prepared as directed in the drug labeling at time of dispensing.

(d) Provide for suitable expiration dates to appear in the labeling of the drug when needed to assure that the drug meets appropriate standards of identity, strength, quality, and purity at time of use.

§ 133.14 Complaint files.

Records shall be maintained of all written or verbal complaints for each product. Complaints shall be evaluated by competent and responsible personnel and, where indicated, appropriate action taken. The record shall indicate the evaluation and action.

Effective date: This order shall become effective on date of publication.

(Secs. 501, 701, 52 Stat. 1050 as amended 76 Stat. 780, 781; 1055 21 U.S.C.A. 351, 371)

It is recognized that some modification of these regulations is indicated in connection with their application to the manufacture of chemicals and other raw materials used as components of finished drugs and in connection with their application to the production of such drugs as medicated feeds for administration to animals, in which current practice involves less rigid conditions. Proposed regulations dealing with these areas will be published at a later date.

Dated: June 12, 1963.

GEO. P. LARRICK,
Commissioner of Food and Drugs.

[F.R. Doc. 63-6336; Filed, June 19, 1963; 8:45 a.m.]